The Global Language of Business

Leveraging GDSN for the FDA Global Unique Device Identifier Database (GUDID) Implementation Guideline

Implementation guide for using the GDSN to populate a UDI database. This version focuses on the U.S. FDA Global Unique Device Identifier Database (GUDID)

Release 2.0, Ratified, Oct 2015

Document Summary

Document Item	Current Value
Document Name	Leveraging GDSN for the FDA Global Unique Device Identifier Database (GUDID) Implementation Guideline
Document Date	Oct 2015
Document Version	2.0
Document Issue	
Document Status	Ratified
Document Description	Implementation guide for using the GDSN to populate a UDI database. This version focuses on the U.S. FDA Global Unique Device Identifier Database (GUDID)

Contributors

Name	Organisation
Pete Alvarez	GS1 Global Office
Scott Brown	GS1 US
John Ryu	GS1 Global Office

Log of Changes

Release	Date of Change	Changed By	Summary of Change
1	09-Sep-2013	Pete Alvarez	Merger of sections created by Pete Alvarez (Global Office) and Scott Brown (GS1 U.S.)
2	06-Jan-2014	Scott Brown	Updated section, GDSN to GUDID Attribute Mapping and Guidance on Populating Attributes per latest FDA GUDID requirements and User Guide
3	08-Jan-2014		Final Review prior to submitting into the GSMP

© 2015 GS1 AISBL

4	20-May-2014	Scott Brown	Updated spelling errors, and grammatical errors throughout the document. Updated cover, header, and footer areas to reflect the change in version, and that the version is a Draft and still needs IP review and ratification to occur. Updated Section 3 (page 23), updated the table legend with corrected headers based on the FDA GUDID Guidance document. Updated Section 3 (page 24), updated a note regarding the FDA GUDID Guidance document and the updating of this document to reflect changes in the FDA Documents. Updated Section 3 (pages 25-57), listing of attributes with various changes. Primarily changing the content from the FDA GUDID Guidance documents such as values for the GUDID of Attribute Name Description, Data Entry Notes, Edit Rules After Grace Period, Required?, Data Type & Length, and Entry List of Values (LOV), values for the GDSN of New Attributes, and Guidance. There are also various formatting and spelling changes throughout this section. All changes are in red text and highlighted in yellow. Some changes denote a difference in the FDA GUDID Webtool Guidance and Guidance for the use of HL7 SPL messaging (machine connection to the FDA GUDID). To aid readability and printability, pagination was also changed to allow for each different attribute to start a new page. Updated Section 4 (pages 59-74), various changes such as updating the GUDID attribute name to match previous sections, equivalent GDSN attributes, GDSN definitions, and GDSN Notes have been made, all changes are in red text with yellow highlighting. Updated Section 5 (pages 75-112), various changes such as updating the GUDID attribute name to match previous sections, GUDID code values, and equivalent GDSN Code Values have been made, all changes are in red text with yellow highlighting. There are several code values which have notes as to change request activity with GSMP, when this work completes the document will be updated. Updated Section 5 (pages 113- 161), the Unit of Measure (UoM) section of the code value table was completely redone, specific additions and mapping have been highlighted in red text with yellow highlighting. The table reflects several new columns in use by the GDA GUDID Guidance documents and similar columns in use by GDSN. Updated Section 6 (pages 162-260), listing of attributes with various changes. Primarily changing the content from the FDA GUDID Guidance documents such as values for the GUDID of Attribute Name Description, Data Entry Notes, Edit Rules After Grace Period, Required?, Data Type & Length, and Entry List of Values (LOV), values for the GDSN of New Attributes, and Guidance. There are also various formatting and spelling changes throughout this section. All changes are in red text and highlighted in yellow. Some changes denote a difference in the FDA GUDID Webtool Guidance and Guidance for the use of HL7 SPL messaging (machine connection to the FDA GUDID). To aid readability and

© 2015 GS1 AISBL

			printability, pagination was also changed to allow for each different attribute to start a new page. Updated Section 7 (page 261), added a reference to a companion GS1 US document which is a spreadsheet mapping tool. Specific changes based on changes made in companion GS1 US documentation are listed below. These specific changes match to the general summary changes listed above. Updated attribute name for the additional classification agency to correct attribute name of additionalClassificationAgencyName Updated the guidance for the attribute manufacturerDeclaredReusabilityType to reflect changes made to the code list tab in the previous version of this sheet Change the code list mapping for the UNKNOWN code value for the serialNumberLocationCode to be TRUE for the GUIDE Corrections to the sheet - Added an AVP for the FDA Medical Device Listing Number which was missing from the sheet - Removed extraneous word "Maximum" in the GDSN attributes for the transportation humidity attribute labels on the Storage and Handling Type tab Corrections to the sheet - Updated code lists with missing values- Additional Classification Code List, Corrections to the sheet - Updated the name of the FDA Premarket Submission Number in the FDA GUDID Column on the additional trade item classification agency tab. Enter comment about name and definition changes being requested in GDSN. - Change the attribute used for the FDA GUDID Publish date from effectiveDate to be fDAGUDIDPublishDate (AVP) and a final trading partner dependent deployment of uDIDPublishDate. - Updated the GDSN Notes for the GMDN Preferred Term and Definition attributes Corrections to the sheet - Corrected the MRI Compatibility codes to be all capitals Corrections to the sheet - Updated the guidance on the use of the Sterility codes - Added code value of KIT_AND_COMBINATION to denote a TRUE value for both TRUE and COMBINATION Corrections to the sheet - Corrected GDSN Definitions for the additionalClassificaitonAgency which incorrectly only referenced Premarket Authorization Numbers - Corrected truncated definitions in the packaging type code list - Corrected the MRI Compatibility code for the GDSN from MRI_CONDITIONAL to the correct value from the GDSN Schema of MRI_COMPATIBLE - Corrected missing words in the FDA Required column foe Supplement Number to complete phrase to state "Not Required for Kits." - Updated guidance on how to populate the FDA Premarket Submission Number and its associate

© 2015 GS1 AISBL

			Supplement Numbers. - Corrected the name of the Additional Classification header on the Additional Classification Agency code list tab to be "Additional Classification Agency Name" Corrections to the sheet - Corrected the case for the clinical size text code list to be upper case - Corrected the data type of the GDSN attribute fDAMedicalDeviceListing (AVP) to alphanumeric (7characters) - Updated process for Premarket Submissions numbers and their related Supplement numbers. Supplement numbers must be associated with an applicable Premarket Submission Number - Updated sheet based on updated guidance from the SPL Guide version 1.2 published by the FDA on 4/16/2014 - Added a column for the SPL XPaths - Added validation guidance for MR Safety Status - Updated UoM sheet to group codes for clinical size types, highlighted GDSN codes to be removed in the GDSN Major Release, and highlights FDA GUDID Codes (including GDSN Change Request to add) - Added tab containing guidance from the FDA on Premarket Submission Number formats - Added new attributes for the Donation Identification Number, FDA Preferred Term Code (including GDSN Change Request to add) - Noted that the GUDID Attribute Is the device labeled for MRI Safety? Is no longer supported in the SP - Added a column to denote the SPL XPath for the attribute -Throughout document where the SPL Information is different from the GUDID Web Guideline document, the SPL information has been added in red text. If the either document is amended to match the other, the extra text will be removed. The following are specific changes made: - Updated the GUDID Data Element field with the SPL Name for- Support Contact Phone, Support Contact Email, Code (Split into two parts- GMDN Preferred Term Code and a new attribute FDA Preferred Term Code), MRI Safety Status, Size Type Text, Storage and Handling Type, High Value, Low Value, Unit of Measure - Updated the GUDID Definition field with SPL Definition for- Labeler DUNS Number, Secondary DI Number, Contains DI Package, Support Contact Phone, Support Contact Email, Device Exempt from Premarket Submission, Supplement Number, Product Code, Code (Split into two parts- GMDN Preferred Term Code and a new attribute FDA Preferred Term Code), Lot or Batch Number, Manufacturing Date, Serial Number, Expiration Date, Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437), Device labeled as "Not made with natural rubber latex", MRI Safety Status, Size Unit of Measure, Storage and Handling Type, High Value, Low Value, Unit of Measure, Special Storage Conditions - Updated the GUDID Required? Field with the SPL Text for- Package DI Number, Contains DI Package, Package Discontinue Date, Support Contact Phone, Support Contact Email, Code

© 2015 GS1 AISBL

			(Split into two parts- GMDN Preferred Term Code and a new attribute FDA Preferred Term Code), MRI Safety Status, Size Type, Size Value, Size Unit of Measure, Size Type Text, Storage and Handling Type, High Value, Low Value, Unit of Measure, Sterilization Method Updated the GUDID Cardinality field with the SPL Text for- Device Subject to Direct Marking (DM), but Exempt, DM DI Number, Secondary DI Number, Package DI Number, Contains DI Package, Support Contact Phone, Support Contact Email, Device Exempt from Premarket Submission, FDA Premarket Submission Number, Supplement Number, Product Code, Code (Split into two parts- GMDN Preferred Term Code and a new attribute FDA Preferred Term Code), MRI Safety Status, Size Type, Size Value, Size Unit of Measure, Size Type Text, High Value, Low Value, Unit of Measure, Special Storage Conditions, Sterilization Method Updated the GUDID Data Type field with the SPL Text for- Version or Model Number, Device Description, DI Record Publish Date (Note: date format is different between the Web Portal and the SPL Message), Commercial Distribution End Date (Note: date format is different between the Web Portal and the SPL Message), Package DI Number, Package Discontinue Date (Note: date format is different between the Web Portal and the SPL Message), Support Contact Phone, Device Exempt from Premarket Submission, Supplement Number, Product Code, Code (Split into two parts- GMDN Preferred Term Code and a new attribute FDA Preferred Term Code), MRI Safety Status, Storage and Handling Type, Unit of Measure Updated the GUDID Length field with SPL text for- Primary DI Number, Unit of Use DI Number, DM DI Number, Secondary DI Number, Package DI Number, Contains DI Package, Device , Code (Split into two parts- GMDN Preferred Term Code and a new attribute FDA Preferred Term Code)Exempt from Premarket Submission, FDA Premarket Submission Number, Supplement Number, Product Code, MRI Safety Status, Storage and Handling Type, Unit of Measure Updated the GUDID Values/Terminology field with the SPL Text for- Device Exempt from Premarket Submission - Added, updated, and deleted codes values for the Clinical Size Type- Angle, Area/SurfaceArea, Outer Diameter, Pore Size, Pressure, and Width Corrected some of the tabs which did not update correctly with the information above- primarily code list tabs for sterilization, and MRI Safety. Corrected incorrect GUDID Occurrence notes in column O for Secondary DI attributes, Package DI attributes, MRI Safety, Clinically Relevant Size attributes, Storage and Handling attributes. Removed highlighted text and cells which represented the changes made between version 12 and 13 of this spreadsheet. Updated sheet to reflect changes in the FDA Appendix B document posted on May 7, 2014 - All changes are noted with red text and a yellow highlighted cell - Updated the GUDID Data Element field with

© 2015 GS1 AISBL

			name changes for Version or Model Number to be Version or Model, Device Description (max 2000 characters) to be Device Description, DI Record Publish Date (mm/dd/yyyy) to be DI Record Publish Date, Commercial Distribution End Date (mm/dd/yyyy) to be Commercial Distribution End Date, Secondary DI Issuing Agency to be Issuing Agency, Heading of Support Contact to be Customer Contact, Support Contact Phone to be Customer Contact Phone, Support Contact Email to be Customer Contact Phone, and MRI Safety Status to be What MRI safety information does the labeling contain? Updated the GUDID Description field with updated definitions for Primary DI Number, Device Count, Labeler DUNS Number, Company Name, Company Physical Address, Version or Model, DI Record Publish Date, Heading Package DI, Package DI Number, Quantity per Package, Contains DI Package, Package Status, Customer Contact Phone, Customer Contact Email, Supplement Number, Product Code, Code, Name, Definition, Lot or Batch Number, Manufacturing Date, Serial Number, Expiration Date, Donation Identification Number, Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437), Device labeled as "Not made with natural rubber latex", Size Type Text, and Unit of Measure Updated the GUDID Data Entry Notes field with updated notes for Issuing Agency, Primary DI Number, Device Count, Unit of Use DI Number, Labeler DUNS Number, Company Name, Company Physical Address, Brand Name, Version or Model, Catalog Number, DI Record Publish Date, Commercial Distribution End Date, Commercial Distribution Status, Heading Direct Marking (DM), Device Subject to Direct Marking (DM), but Exempt, DM DI Number, Issuing Agency, Secondary DI Number, Package DI Number, Quantity per Package, Contains DI Package, Package Type, Package Discontinue Date, Package Status, Customer Contact Phone, Customer Contact Email, Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P), Kit, Combination Product, Device Exempt from Premarket Submission, FDA Premarket Submission Number, Supplement Number, Product Code, Product Code Number, FDA Listing Number, Code, Name, Definition, For Single- Use, Lot or Batch Number, Manufacturing Date, Serial Number, Expiration Date, Donation Identification Number, Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437), Device labeled as "Not made with natural rubber latex", Prescription Use (Rx), Over the Counter (OTC), MRI Safety Information, Size Type, Size Value, Size Type Text, Storage and Handling Type, High Value, Low Value, Unit of Measure, Special Storage Conditions, Device Packaged as Sterile, Requires Sterilization Prior to Use, and Sterilization Method. Updated the GUDID Edit Rules after Grace Period and GUDID Required in Database fields for all GUDID Attributes.

© 2015 GS1 AISBL

Release	Date of Change	Changed By	Summary of Change
			Change name of the GUDID Required? column to be GUDID Required in Database?, Removed the GUDID Cardinality column. Merged the GUDID Data Type and GUDID Length columns into one column titled GUDID Data Type & Length. Updated the values for all GUDID attributes for the Data Type and Length column Updated the column heading GUDID Values/ Terminology to be GUDID Entry List of Values (LOV). Updated the values for all GUDID attributes for the GUDID Entry List of Values (LOV) column. Updated the New DI Trigger? field for the attributes Requires Sterilization Prior to Use Added new attribute information for the attribute Donation Identification Number. Marked the attribute Is the device labeled for MRI Safety? as being deleted Removed columns L and M for GUDID Required and GUDID Occurrence. These columns had been repeated from the left side of the spreadsheet as a convenience when the sheet was shifted to view the columns on the right side. This was causing issues and the columns are removed as redundant information. Updated tab containing the Sterilization Method codes to detail all requested GDSN codes and the FDA value of Liquid Chemical can be aligned with FORMALDEHYDE, GLUTERALDEHYDE, and ETHANOL Updated Logo to new GS1 US logo

© 2015 GS1 AISBL

4	09-May-2014	Scott Brown	Updated the following sections 3, 4, 5 to align document with the release of the FDA GUDID SPL version 1.2.1 issued on April 16, 2014 Added validation guidance for MR Safety Status Updated UoM list to group codes for clinical size types, highlighted GDSN codes to be removed in the GDSN Major Release, and highlights FDA GUDID Codes (including GDSN Change Request to add) Added tab containing guidance from the FDA on Premarket Submission Number formats Added new attributes for the Donation Identification Number, FDA Preferred Term Code (including GDSN Change Request to add) - Noted that the GUDID Attribute Is the device labeled for MRI Safety? Is no longer supported in the SP Throughout document where the SPL Information is different from the GUDID Web Guideline document, the SPL information has been added in highlighted red text. If either document is amended to match the other, the text will be edited to match the changes. The following are specific changes made: Updated the GUDID Data Element field with the SPL Name for- Support Contact Phone, Support Contact Email, Code (Split into two parts- GMDN Preferred Term Code and a new attribute FDA Preferred Term Code), MRI Safety Status, Size Type Text, Storage and Handling Type, High Value, Low Value, Unit of Measure Updated the GUDID Definition field with SPL Definition for- Labeler DUNS Number, Secondary DI Number, Contains DI Package, Support Contact Phone, Support Contact Email, Device Exempt from Premarket Submission, Supplement Number, Product Code, Code (Split into two parts- GMDN Preferred Term Code and a new attribute FDA Preferred Term Code), Lot or Batch Number, Manufacturing Date, Serial Number, Expiration Date, Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437), Device labeled as "Not made with natural rubber latex", MRI Safety Status, Size Unit of Measure, Storage and Handling Type, High Value, Low Value, Unit of Measure, Special Storage Conditions Updated the GUDID Required? Field with the SPL Text for- Package DI Number, Contains DI Package, Package Discontinue Date, Support Contact Phone, Support Contact Email, Code (Split into two parts- GMDN Preferred Term Code and a new attribute FDA Preferred Term Code), MRI Safety Status, Size Type, Size Value, Size Unit of Measure, Size Type Text, Storage and Handling Type, High Value, Low Value, Unit of Measure, Sterilization Method Updated the GUDID Cardinality field with the SPL Text for- Device Subject to Direct Marking (DM), but Exempt, DM DI Number, Secondary DI Number, Package DI Number, Contains DI Package, Support Contact Phone, Support Contact Email, Device Exempt from Premarket Submission, FDA Premarket Submission Number, Supplement Number, Product Code, Code (Split into two parts- GMDN Preferred Term Code and a new attribute FDA Preferred Term Code), MRI

© 2015 GS1 AISBL

Release	Date of Change	Changed By	Summary of Change
			Safety Status, Size Type, Size Value, Size Unit of Measure, Size Type Text, High Value, Low Value, Unit of Measure, Special Storage Conditions, Sterilization Method Updated the GUDID Data Type field with the SPL Text for- Version or Model Number, Device Description, DI Record Publish Date (Note: date format is different between the Web Portal and the SPL Message), Commercial Distribution End Date (Note: date format is different between the Web Portal and the SPL Message), Package DI Number, Package Discontinue Date (Note: date format is different between the Web Portal and the SPL Message), Support Contact Phone, Device Exempt from Premarket Submission, Supplement Number, Product Code, Code (Split into two parts- GMDN Preferred Term Code and a new attribute FDA Preferred Term Code), MRI Safety Status, Storage and Handling Type, Unit of Measure Updated the GUDID Length field with SPL text for- Primary DI Number, Unit of Use DI Number, DM DI Number, Secondary DI Number, Package DI Number, Contains DI Package, Device , Code (Split into two parts- GMDN Preferred Term Code and a new attribute FDA Preferred Term Code)Exempt from Premarket Submission, FDA Premarket Submission Number, Supplement Number, Product Code, MRI Safety Status, Storage and Handling Type, Unit of Measure Updated the GUDID Values/Terminology field with the SPL Text for- Device Exempt from Premarket Submission Added, updated, and deleted codes values for the Clinical Size Type- Angle, Area/Surface Area, Outer Diameter, Pore Size, Pressure, and Width

© 2015 GS1 AISBL

Release	Date of Change	Changed By	Summary of Change
5	09-May-2014	Scott Brown	Corrections to the document sections 3, 4, 5 to correct the following- Corrected the case for the clinical size text code list to be upper case Corrected the data type of the GDSN attribute fDAMedicalDeviceListing (AVP) to alphanumeric (7characters) Updated process for Premarket Submissions numbers and their related Supplement numbers. Supplement numbers must be associated with an applicable Premarket Submission Number Updated the name of the FDA Premarket Submission Number in the FDA GUDID Column on the additional trade item classification agency tab. Enter comment about name and definition changes being requested in GDSN. Change the attribute used for the FDA GUDID Publish date from effectiveDate to be fDAGUDIDPublishDate (AVP) and a final trading partner dependent deployment of uDIDPublishDate. Updated the GDSN Notes for the GMDN Preferred Term and Definition attributes" Corrected the MRI Compatibility codes to be all capitals" Updated the guidance on the use of the Sterility codes Added code value of KIT_AND_COMBINATION to denote a TRUE value for both TRUE and COMBINATION" Corrected GDSN Definitions for the additionalClassificaitonAgency which incorrectly only referenced Premarket Authorization Numbers Corrected truncated definitions in the packaging type code list Corrected the MRI Compatibility code for the GDSN from MRI_CONDITIONAL to the correct value from the GDSN Schema of MRI_COMPATIBLE Corrected missing words in the FDA Required column foe Supplement Number to complete phrase to state "Not Required for Kits." Updated guidance on how to populate the FDA Premarket Submission Number and its associate Supplement Numbers. Corrected the name of the Additional Classification header on the Additional Classification Agency code list tab to be "Additional Classification Agency Name"
6	01-Jul-2014	Pete Alvarez	Replaced the GS1 DataMatrix example in section 1.3.3.

© 2015 GS1 AISBL

Release	Date of Change	Changed By	Summary of Change
Release 1.2 Draft 1	15-Jul-2014	John Ryu	Incorporate WR 14-103 and 14-111 WR 14-103 Corrections to the sheet Updated the GDSN note for the Labeler DUNS number. Brand Owner GLN is a GDSN Mandatory field and the additional Party Identification attributes will be linked to the Brand Owner GLN specifically Change the approach for the FDA Device Count. A new GDSN attribute has been requested and this value will no longer be derived from the attribute netContent. An AVP has been put in place to support this until full GDSN deployment. netContent will be moved from the FDA GUDID Mapping area to the supply chain area at the bottom of the spreadsheet. Updated the FDA Attribute name for the DI Publish Date the Discontinue Date which were missing the format.\ WR 14-111 Corrections to the sheet Added several AVPs to support new sterilization methods until GDSN can deploy the codes.- isInitialSterilisationPriorToUseChlorineDioxide, isInitialSterilisationPriorToUseDryHeat, isInitalStrilistonPriorHighIntensityOrPulseLight, isInitialSterilisationPriorToUseMicrowaveRadiation, isInitialSterilisationPriorToUseSoundWaves, isInitialSterilisationPriorHighLevelDisinfectant, isInitialSterilisationPriorToUseLiquidChemical, isInitialSterilisationPriorToUseNitrogenDioxide, isInitalStrilistonPrirSupercriticalCarbonDioxide
Release 1.2 Issue 1	22-August-2014	John Ryu	eBallot Approved and closed IP review Publication Update: Added tables into section 6 Guidance on Populating Values for ease of readability. Removed strikethrough text [example: ~~(mm/dd/yyyy)~~ (yyyy-mm-dd)]
Release 1.2 Issue 1	6-Nov-2014	David Buckley	Ratified version
Release 1.3 Draft 1	9 January 2015	Pete Alvarez	Clarification regarding the use of a GDSN Data Pool to register data in the U.S. FDA GUDID Updated Section 1: Introduction 2: GDSN Data Flow 7: Reference Document Title change: From: GDSN for the FDA Global Unique Device Identifier Database (GUDID) TO: Leveraging GDSN for the FDA Global Unique Device Identifier Database (GUDID)

© 2015 GS1 AISBL

Release 1.3 Draft 2	28 January 2015	John Ryu based on Scott Brown's spreadsheet 20150126 V20	Changes to sheet based on changes made by FDA to their documentation. Added phrase "Must be from same Issuing Agency as Primary DI." to the GUDID Data Entry Notes for the FDA Attribute Unit of Use DI Number. Added phrase "Must be from same Issuing Agency as Primary DI." to the GUDID Data Entry Notes for the FDA Attribute DM DI Number. Added phrase "Must be from same Issuing Agency as Primary DI." to the GUDID Data Entry Notes for the FDA Attribute Unit of Package DI Number. Removed the date format tag "(yyyy-mm-dd) from the name of the FDA GUDID Attributes DI Record Publish Date and Commercial Distribution End Date Updated the SPL Attribute Name for the FDA GUDID Attribute Issuing Agency in the Secondary DI section to be "Issuing Agency of Secondary DI" Updated the last line in the GUDID Data Entry Notes for the FDA Attribute Customer Contact Email to be "If a phone number is entered and you don't have a Customer Contact email, please enter 'xx@xx.xx'" Removed the SPL Attribute Name for the FDA GUDID Attributes Customer Contact Phone and Customer Contact Email Renamed SPL Attribute name of the FDA: Support Contact Phone to Customer Contact Phone Updated the length of the FDA Attribute Premarket Submission Supplement Number to be "Length = CDRH 1-3 digits, CBER 1-4 digits" Updated the GUDID Data Entry notes for the FDA Attribute GMDN Code to be "Enter all applicable GMDN Preferred Term Codes or FDA PT Codes. Each device record must have at least one assigned GMDN Code/FDA PT Code; DI records are allowed >1 GMDN Code/FDA PT Code, if necessary. Must enter GMDN Code OR FDA PT Code, please don't enter both codes for the same GMDN Name and Definition. For GMDN Codes: Enter only the 5-digit number, omit the 'P' For FDA PT Codes: Enter the 4-letter code. The FDA PT Codes are assigned to each GMDN term, used in place of a GMDN Code. They enable labelers to assign a GMDN term to their GUDID submission until a GMDN Code can be obtained from the GMDN Agency. The FDA PT Codes can be found in the Find FDA PT Code Module on the GUDID website. For more information, see the GUDID Final Guidance. The FDA PT Codes can be found in the Find FDA PT Code Module on the GUDID website." Changed section heading from "Production Identifier(s) on Label" to "Production Identifier(s) in UDI" Updated list of values for the FDS Attribute Size Unit of Measure -- Added Millibar for pressure; and Removed -- Microgram per Total Volume; Milligram per Total Volume Updated the GUDID Data Entry notes for the FDA Attribute Low Value to be "Enter a number for

© 2015 GS1 AISBL

Release	Date of Change	Changed By	Summary of Change
			Low Value. Must enter at least one value, Low or High but can enter both Low Value and High Value, if needed. When Storage and Handling value is a range, this is the lower end of that range When Storage and Handling value is less than a value, enter the number here. When Storage and Handling value is exactly a value, enter the value here and in Storage and Handling High Value" Updated the GUDID Data Entry notes for the FDA Attribute High Value to be "Enter a number for High Value. Must enter at least one value, Low or High but can enter both Low Value and High Value, if needed. When Storage and Handling value is a range, this is the higher end of that range. When Storage and Handling value is greater than a value, enter the number here. When Storage and Handling value is exactly a value, enter the value here and in Storage and Handling Low Value." Updated the list of values for the FDA Attribute Storage and Handling Unit of Measure-- Added Millibar for Storage and Handling Pressure Removed GDSN Attribute TradeItemDescription/text from the attributes for concatenation into the FDA GUDID Attribute Device Description Added GDSN notes for the GDSN attribute initialSterilisationPriorToUse
Release 1.3.1 Draft 1	4 March 2015	John Ryu	WR 15-043 Errata Change Deleted two sentences below. 6.50. What MRI safety information does the labeling contain? Population Guidance (below) This GDSN attribute is a code list of values signifying if the device is safe for use in an MRI environment. All GDSN code values map to an applicable GUDID code value. ~~While it is not recommended to use a GDSN value of UNSPECIFIED as this provides no useful information and can lead to confusion in a clinical setting. However, if a GDSN value of UNSPECIFIED is published, this will be mapped to MR Unsafe as a default~~
Release 1.3.1	May 2015	David Buckley	WR15-183 (Update for major release)
Draft Release 2.0.	Jul 2015	Valerie Hoste	Applied new GS1 branding prior
Release 2.0	Oct 2015	David Buckley	WR15-290 (Errata approval of branding at 29 Sep 2015 SMG call)

Disclaimer

GS1®, under its IP Policy, seeks to avoid uncertainty regarding intellectual property claims by requiring the participants in the Work Group that developed this **Leveraging GDSN for the FDA Global Unique Device Identifier Database (GUDID) Implementation Guideline** to agree to grant to GS1 members a royalty-free licence or a RAND licence to Necessary Claims, as that term is defined in the GS1 IP Policy. Furthermore, attention is drawn to the possibility that an implementation of one or more features of this Specification may be the subject of a patent or other intellectual property right that does not involve a Necessary Claim. Any such patent or other intellectual property right is not subject to the

 © 2015 GS1 AISBL

licencing obligations of GS1. Moreover, the agreement to grant licences provided under the GS1 IP Policy does not include IP rights and any claims of third parties who were not participants in the Work Group.

Accordingly, GS1 recommends that any organization developing an implementation designed to be in conformance with this Specification should determine whether there are any patents that may encompass a specific implementation that the organisation is developing in compliance with the Specification and whether a licence under a patent or other intellectual property right is needed. Such a determination of a need for licencing should be made in view of the details of the specific system designed by the organisation in consultation with their own patent counsel.

THIS DOCUMENT IS PROVIDED “AS IS” WITH NO WARRANTIES WHATSOEVER, INCLUDING ANY WARRANTY OF MERCHANTABILITY, NONINFRINGMENT, FITNESS FOR PARTICULAR PURPOSE, OR ANY WARRANTY OTHER WISE ARISING OUT OF THIS SPECIFICATION. GS1 disclaims all liability for any damages arising from use or misuse of this Standard, whether special, indirect, consequential, or compensatory damages, and including liability for infringement of any intellectual property rights, relating to use of information in or reliance upon this document.

GS1 retains the right to make changes to this document at any time, without notice. GS1 makes no warranty for the use of this document and assumes no responsibility for any errors which may appear in the document, nor does it make a commitment to update the information contained herein.

GS1 and the GS1 logo are registered trademarks of GS1 AISBL.

Table of Contents

1 Introduction 18

1.1 Purpose of this Document 18
1.2 Who Will Use this Document? 18
1.3 Prerequisite 18
1.3.1 The GS1 Global Company Prefix (GCP) 18
1.3.2 Role of the Global Trade Item Number (GTIN) and Application Identifiers (AIs) 18
1.3.3 Automatic Identification and Data Capture (AIDC) Marking 19
1.3.4 The role of Global Location Number (GLN) in UDI 19
1.3.5 GDSN Knowledge 19
1.4 What is UDI and (G)UDID 19
1.5 Master Data Management and Governance 20
1.6 Data Quality 20
1.7 Data Management 21
1.8 Data Governance 22
1.9 Roles and Responsibilities 23

2 GDSN Data Flow 23

3 GUDID Data Requirements 25

4 GS1 GDSN to FDA GUDID Mapping 65

5 FDA GUDID Mapping to GS1 Code Values 91

6 Guidance on Populating Values 147

6.1 Issuing Agency 147
6.2 Primary DI# 148
6.3 Device Count 148
6.4 Unit of Use DI# Number 149
6.5 Labeler DUNS Number 151
6.6 Company Name 152
6.7 Company Physical Address 153
6.8 Brand Name 154
6.9 Version or Model 155
6.10 Catalog Number 156
6.11 Device Description 157
6.12 DI Record Publish Date 158
6.13 Commercial Distribution End Date 159
6.14 Commercial Distribution Status 160
6.15 Device Subject to Direct Marking (DM), but Exempt 160
6.16 DPM DI Different from Primary DI 161
6.17 DPM DI Number 162
6.18 Issuing Agency 164
6.19 Secondary DI Number 165
6.20 Package DI Number 166
6.21 Quantity per package 168
6.22 Contains DI Package 170

© 2015 GS1 AISBL

6.23 Package Type 172
6.24 Package Discontinue Date 173
6.25 Package Status 174
6.26 Customer Contact Phone 174
6.27 Customer Contact Email 176
6.28 Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P) 177
6.29 Kit 178
6.30 Combination Product 179
6.31 Device Exempt from Premarket Authorization 180
6.32 FDA Premarket Submission Number 181
6.33 Supplement # 183
6.34 Product Code 184
6.35 Product Code Name 185
6.36 FDA Listing Number 186
6.37 Code SPL Name - GMDN Preferred Term Code and FDA Preferred Term Code 187
6.38 Name 189
6.39 Definition 189
6.40 For Single Use 190
6.41 Lot or Batch Number 191
6.42 Manufacture Date 192
6.43 Serial Number 193
6.44 By Expiration Date 194
6.45 Donation Identification Number 194
6.46 Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437) 195
6.47 Device labeled as "Not made with natural rubber latex" 196
6.48 Prescription Use (Rx) 197
6.49 Over the Counter (OTC) 198
6.50 What MRI safety information does the labeling contain? 199
6.51 Size Type 200
6.52 Size Value 201
6.53 Size Unit of Measure 202
6.54 Size Type Text SPL Name: “Size Text” 203
6.55 Storage and Handling Type 204
6.56 Low Value SPL Name: "Storage and Handling Low Value" 207
6.57 High Value SPL Name: "Storage and Handling High Value" 210
6.58 Unit of Measure SPL Name: "Storage and Handling Unit of Measure" 212
6.59 Device Packaged as Sterile 215
6.60 Requires Sterilization Prior to Use 216
6.61 Sterilization Method 217

7 References 218

 © 2015 GS1 AISBL

1 Introduction

1.1 Purpose of this Document

The purpose of this document is to explain how to leverage the Global Data Synchronization Network (GDSN) infrastructure to securely provide data to a Unique Device Identification (UDI)) database. The first version of this implementation guide will focus on the U.S. FDA Global Unique Device Identifier Database (GUDID) requirements since this is the only regulator to issue a UDI rule for medical devices as of this writing. As other regulators introduce UDI regulation this document will be updated as needed.

1.2 Who Will Use this Document?

This document is intended primarily for medical device Brand Owners who have decided to use GS1 standards to comply with UDI regulation and the GDSN Data Pools who will be required by the medical device customers to provide data on their behalf to a UDI database.

The guidance and GDSN attributes included in this document is based on the published database requirements and GUDID Users' Guide from the U.S. FDA, plus the lessons learnt from the GDSN pilot held as part of the U.S. FDA User Acceptance testing of 2012. This document contains addition guidance on Master Data Management and Governance plus Information Lifecycle Management and Data Quality. This information is intended as general guidance for the purpose of assisting GS1 members. The UDI regulation may contain specific information related to the rule, which in case of conflict supersedes this general guidance.

1.3 Prerequisite

It is assumed that the reader is already familiar with the UDI regulation and the database requirements prior to using this implementation guide. For additional information on UDI visit the *GS1 UDI webpage* or the website of the specific regulation in question.

Below are a few basics steps the Medical Device Brand Owner should consider prior to using their GDSN Data Pool to register their medical device product data in the appropriate UDI database. The section includes prerequisites for using GS1 standards to implement a UDI regulation.

1.3.1 The GS1 Global Company Prefix (GCP)

The GS1 Global Company Prefix is the base component used to create a GS1 Key such as a Global Trade Item Number (GTIN). The GS1 Global Company Prefix is a license to create GS1 Keys and is issued by any one of the GS1 Member Organisations to companies who wish to use the GS1 system.

The GS1 website lists *10 basic steps to barcode implementation* and is offered as a guide for getting started. For additional information regarding your GS1 Company Prefix and GS1 standards contact your local *GS1 Member Organisation by visiting the GS1 website.*

1.3.2 Role of the Global Trade Item Number (GTIN) and Application Identifiers (AIs)

The Global Trade Item Number (GTIN), as the GS1 trade item "Identification Key", is used to identify medical devices, identifying different product variants and each package configuration to achieve unique and unambiguous identification. The UDI includes at a minimum the "static" portion, a "Device Identifier" (DI), as its "key" to specific device related information stored in a database. The GTIN is the GS1 solution for creating the Device Identifier component of a UDI and accessing medical device information stored in a database.

The Unique Device Identifier also includes a 'dynamic' portion, known as the "Production Identifier", to represent production control information generated as part of the manufacturing process based upon the specific medical device. This Production Identifier (PI) can include, for example, manufacturing date, expiry date, lot number or serial number. GS1 Application Identifiers (AIs) are the GS1 solution for creating the Production Identifier component of a UDI.

Note: the Production Identifier portion of a UDI is NOT stored in a UDI database.

© 2015 GS1 AISBL

Additional information regarding the use of the GS1 GTIN and Application Identifiers can be found in the GS1 General Specifications, GS1 Healthcare GTIN Allocation Rules and GS1 UDI support materials (*http://www.gs1.org/healthcare/udi*).

1.3.3 Automatic Identification and Data Capture (AIDC) Marking

Marking of the UDI on the medical device packaging (and in some cases the medical device itself), via an Automatic Identification and Data Capture (AIDC) "Data Carrier" technology is a primary requirement of the U.S. FDA UDI ruling. The Data Carrier is the means used to transport the UDI with the medical device and retrieve its unique identification, enabling access to the database stored information. The GS1 System includes specifications for the use of both Barcode and RFID Data Carriers including (but not limited to) EAN/UPC, GS1-128, GS1 DataMatrix Barcode symbologies.

Selection of the appropriate GS1 Data Carrier is based upon a number of factors including the UDI to be encoded in the Data Carrier, the distribution channel of the medical device, available space for the Data Carrier among other criteria of the regulation. Additional information and specifications on the selection and use of GS1 Data Carriers can be found in the GS1 General Specifications and GS1 UDI support materials (*http://www.gs1.org/healthcare/udi*).

For additional information on identification of items below the "each" level refer to the GS1 Healthcare GTIN Allocation Rules (*http://www.gs1.org/1/gtinrules/index.php/p=static/t=healthcare*)

1.3.4 The role of Global Location Number (GLN) in UDI

The Global Location Number is a 13 digit numeric GS1 standard used to identify locations and legal entities. While the U.S. FDA UDI regulation does not require the use of GLNs in order to comply with the rule, it is required when using the Global Data Synchronisation Network (GDSN) to identify the Brand Owner and the data recipients. In addition, the U.S. FDA Global UDI database can be identified by GLN 1100001017041 for GDSN Data Pools who wish to provide this service to their customers. This unique identification ensures that there is a single and unique global identification of the U.S. FDA GUDID within the GDSN Data Pools offering submission and registration of the Brand Owner's medical device product data.

1.3.5 GDSN Knowledge

This guide and the information contained within it require the reader to have a basic understanding of the Global Data Synchronisation Network (GDSN). For more information on the GDSN refer to the *GDSN page* on the GS1 website or contact a *GS1 member Organisation* or a *GDSN certified Data Pool*.

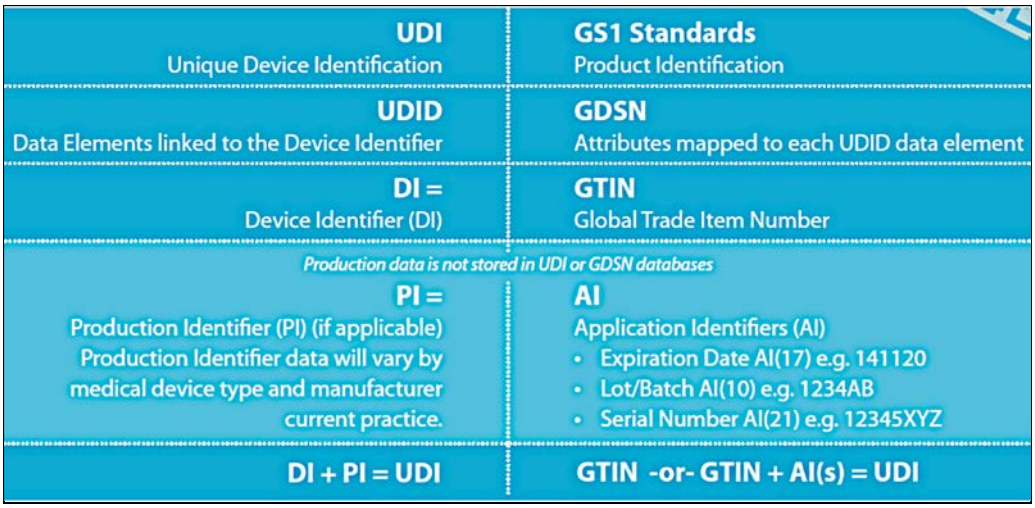
1.4 What is UDI and (G)UDID

The Unique Device Identifier (UDI) is a multinational initiative driven by several medical device regulators with the intention of improving patient safety and healthcare business processes. Each UDI regulation is expected to include a database, which will contain medical device product data. This is referred to as a Unique Device Identifier Database (UDID). For more information in UDI at a global level and how GS1 standards support it refer to the *UDI page on the GS1 website*. The

 © 2015 GS1 AISBL

illustration below provides a basic cross reference between UDI terms and the corresponding GS1 standard.

Figure 1-1


UDI
Unique Device Identification
GS1 Standards
Product Identification
UDID
Data Elements linked to the Device Identifier
GDSN
Attributes mapped to each UDID data element
DI =
Device Identifier (DI)
GTIN
Global Trade Item Number
Production data is not stored in UDI or GDSN databases
PI =
Production Identifier (PI) (if applicable)
Production Identifier data will vary by medical device type and manufacturer current practice.
AI
Application Identifiers (AI)
• Expiration Date AI(17) e.g. 141120
• Lot/Batch AI(10) e.g. 1234AB
• Serial Number AI(21) e.g. 12345XYZ
DI + PI = UDI
GTIN -or- GTIN + AI(s) = UDI

The United States Food and Drug Administration is the first regulator to issue an UDI rule. In addition the U.S. FDA operates a database called Global Unique Device Identifier Database (GUDID) designed to store medical device product data. For more information on the U.S. FDA UDI and GUDID and how GS1 standards support it refer to the *UDI page on the GS1 US website*.

1.5 Master Data Management and Governance

One of the most challenging areas related to implementation of the UDI regulation is the Master Data Management and Governance. Master Data Management and Governance (MDM&G) refers to a series of processes and protocols that should exist within an organisation to create, enrich, maintain and publish product information within and outside the enterprise. Equally important is “data quality management,” which is a complementary cycle of activities aimed to ensure that the subject information meets high standards of quality and reliability. In short, the data created by the product’s Brand Owner must meet the requirements of the intended use case. Medical device data which has to comply with UDI regulation is no exception.

Completeness and accuracy of product data is the responsibility of the Brand Owner. Each Brand Owner should have an internal process to manage the data required by the regulator. This includes:

- data quality checks and procedures
- data management process and policies
- enterprise-wide data governance policies
- roles and responsibilities which outline who has the authority to create, modify and approve the data

GS1 strongly recommends that each Brand Owner ensure they have a robust Information MDM&G and data quality process in place as part of their internal data preparation process.

1.6 Data Quality

Good data quality is a key ingredient of any efficient supply chain. Having the means to continuously maintain high quality data is not only vital to reducing errors and improving patient safety but also to reducing errors in the supply chain. It is also fundamental to increasing efficiency, reducing costs and positively impacting customer satisfaction.

Good quality data means that all master data is complete, consistent, accurate, time-stamped and industry standards-based. By improving the quality of data, trading partners reduce costs, improve productivity and accelerate speed to market.

© 2015 GS1 AISBL

For more information on GS1 data quality best practices and recommendations refer to the *Data Quality page on the GS1 website*

Some regulators may include specific business and data validations to ensure data quality of the information provided by the Brand Owner. Please refer to the specific regulation for more information.

1.7 Data Management

Data Management refers to processes and procedures within an enterprise related to lifecycle information management. In relationship to UDI regulation, this refers to product master data and lifecycle management of the related information. The U. S. FDA regulation contains specific data management requirements and recommendations to which a Brand Owner must adhere. However, this section contains general guidance as a recommendation to augment the requirements of any regulator. In case of conflict, the regulation supersedes this guidance.

Below are seven basic steps of an information lifecycle management process.

1. Create, Import or Receive

The first step is the creation of the product data. This may include gathering information related to the product specifications, raw materials, function, regulatory requirements, and sterilization among other areas. The U.S. FDA GUDID includes a specific list of data requirements and data relationship based on the recommendation from the International Medical Device Regulators Forum (IMDRF), formerly known as the Global Harmonization Task Force plus additional information required by the U.S. FDA. In this step the Brand Owner should confirm the core attributes and match against data requirements of the UDI regulation. Sections 3 and 4 of this document contain a listing of the GUDID data requirements and cross reference to GDSN attributes. The U.S. FDA UDI rule and Users Guide supersedes any information found in this document and will always serve as the point of reference for U.S. FDA UDI requirements.

2. Enrich and Validate

This step refers to an internal process by which the data created in step one is completed with any missing data, validated for compliance with specific requirements of the UDI regulation and approved. This is a fundamental step in data quality management. GS1 offers general data quality guidance and best practices based on industry experience including the GS1 Data Quality Protocol. Below are a few basic steps to consider.

- Completeness: Is data missing which is needed for that specific product?
- Accuracy: Is data precise, correct, and current?
- Conformity: Have formatting rules and standards been applied properly?
- Logic: Is data valid or conflicting across product classes?
- Consistency: Is data consistent across systems for the same field?
- Integrity: Are there appropriate data linkages between internal systems?
- Duplication: Are there unnecessary representations of the same data?

For specific information regarding data quality and validation requirements of the U.S. Global UDI Database refer to FDA regulation and User Guide.

3. Publish and Activate

Once the data is created, enriched, validated and approved it can be published and activated for use. Publication can refer to internal users, catalogues or the GDSN Source Data Pool for data synchronization with external users.

In relationship to UDI, the data should now be ready for registration in the corresponding UDI database, such as the U.S. FDA GUDID. Section two of this document outlines three ways for registering data with the U.S. FDA's GUDID, including how to use a GDSN Data Pool to register the data on behalf of the Brand Owner.

4. Audit and Evaluate

© 2015 GS1 AISBL

Part of the information lifecycle management includes routine monitoring to ensure the data is fit for purpose. This is typically an ongoing process, which is part of a continuous data quality management and improvement process. It can be in the form of an actual audit event, but generally it is part of the user feedback process as a result of application of the information. Ideally the Audit is performed against a set of Metrics or Key performance Indicators. Error investigation should include a route cause analysis to determine the cause of the problem and steps to prevent it from re-occurring. Some organisations include a scorecard to report performance and track improvements over time.

5. Update and Maintain

The information lifecycle management process should include a step to update information as relevant changes occur in any part of the master data. This applies to information about the product as well as well as the organisation. This step should include notification of the change to the data owner for approval.

6. Inactivate and Archive

As information is obsoleted and purged, it should be removed from active use. This may include a flag to indicate that a particular data element is inactive and is no longer used, but it is not removed from the listing. This is a very relevant step in UDI regulation, which requires data which has been made inactive to be permanently stored in a UDI database. In general master data management, the data element can be archived from the internal active database. The determination of which action applies usually depends on particular use case for which the data is intended, such as UDI regulation.

7. Purge

Generally speaking outdated information should be deleted from systems where it has been stored as part of the publication process. This should include the generation of a Purge List, which should be provided to the internal data owners and users. I some cases this may include the approval of the purge by the data owner.

The U.S. FDA UDI rule includes specific requirements regarding the information lifecycle management, which may supersede guidance found in this document. For additional information refer to the U.S. FDA GUDID User's Guide.

1.8 Data Governance

Data governance relates to an enterprise wide process which includes decision authority, policy and issue escalation. An enterprise wide Data Governance process should include data management, data quality, data policies and risk management and executive sponsorship. The process should ensure that certain data assets are formally recognized and managed throughout the organisation.

Data Governance is a critical component of Master Data Management and especially important to the accuracy of the data requirements of a UDI regulation. Each Brand Owner is responsible for submitting and maintaining their data in the UDI database.

Data Governance should include the decision rights and accountability of the key pillars:

- Executive: Internal sponsors of the Master Data Management process within an organisation executive management.
- Legal / Legislative: Internal sponsors responsible for the representation of regulatory affairs as it relates to information management and publication in both internal and external systems and databases. This includes legal compliance, legislative and regulatory requirements. This is especially important with UDI regulation.
- Administrative: Internal function responsible for the maintenance of the Master Data. The function can be either centralized or decentralized.

Refer to the Roles and Responsibilities section of this document for more information in functional responsibilities.

© 2015 GS1 AISBL

1.9 Roles and Responsibilities

The Data Governance policies should include clear determination, documentation and enterprise wide education of the Roles and Responsibilities of each function across the information supply chain. This should include a determination of how data is managed within an organisation and the roles associated with the process. Generally speaking, there are two overarching models, centralized or decentralized. Most commonly, the responsibilities are spread across an entire organisation ranging from manufacturing, to product management to regulatory affairs. Which model applies to a particular organisation depends on many factors, such as organisational structure, size and policies related to corporate versus division autonomy and perhaps even legal incorporation of the various divisions, which make up the organisation.

There are many models for establishing and documenting Roles and Responsibilities. The first step should be to determine if your organisation has a corporate philosophy or policy for assigning roles and responsibilities for information lifecycle management. If not, a basic place to start might be the RACI model.

- **R = Responsible** - owns the project, problem or task. The person responsible for doing the work to achieve the task
- **A =** to whom the R is **Accountable** - who must sign-off (approve) work before it is effective
- **C =** to be **Consulted** – has information and/or capability necessary to complete the work
- **I =** to be **Informed** – must be notified of results, need not be consulted

This simple yet effective model can be applied in any size company. In large organisations, which include divisions in various parts of the world the roles and responsibilities are usually managed in decentralized manner. Conversely, in a small organisation everyone involved in the information management supply chain may be located in a single location. The level of specificity depends on the granularity needed in order for the Master Data Management and Governance process to be effective and for it to meet its intended purpose. For the purpose of UDI regulation, the internal Regulatory Affairs function should be consulted as well.

2 GDSN Data Flow

This section explains how to use the GDSN standard and GDSN certified Data Pools to register product data in the U.S. FDA Global UDI Database (GUDID). This section will be updated as other regulators introduce UDI regulation.

It should be noted that the U.S. FDA does not subscribe to a specific GDSN Data Pool and hence it is not a GDSN Data Recipient in the traditional meaning of this term. This means that GDSN Data Sources cannot expect to publish their item master data to the U.S. FDA using their GDSN home data pool unless an additional service for this is offered by their GDSN Data Pool service provider. However, many labelers are GDSN Data Sources and wish to leverage their GDSN Data Pool to register data in the FDA GUDID in addition synchronising data with data recipients in the GDSN. By doing so, they will be able to leverage their GDSN connection to register data in future UDI database.

As mentioned in section, 1.3.4, the U.S. FDA Global UDI database is identified by GLN 1100001017041 within the GDSN Data Pools offering this service. This unique identification ensures that there is a single and unique global identification of the U.S. FDA GUDID within the entire GDSN community for all Data Pools to use in the submission and registration of the Brand Owner's medical device product data.

Below is a brief overview of options available to labelers for registering their data in the FDA's GUDID.

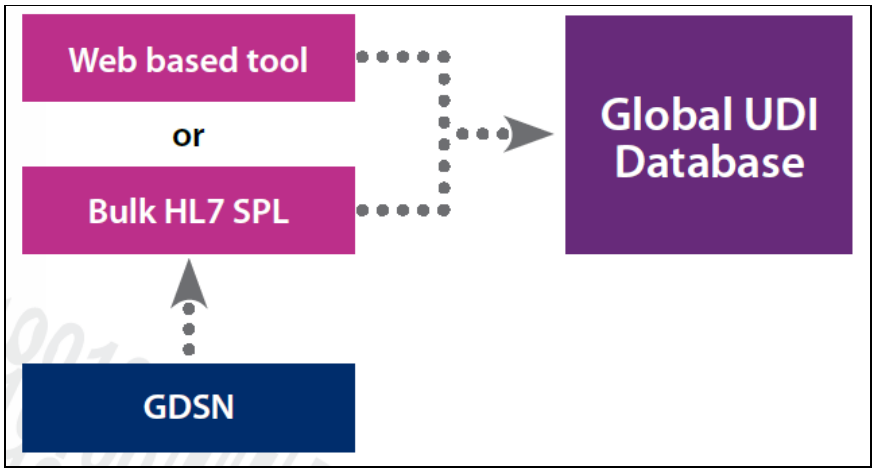
1. Manual data entry via the Web based tool. This refers to a web portal provided by the U.S. FDA to register data directly in their GUDI. The portal provides a means for the medical device Brand Owner to enter and update their data manually directly in their database.
2. Bulk data registration direct from a Brand Owner's internal application using the HL7 standard. This refers to a machine to machine automated method of registering data. It requires the use of the Standard Product Labelling standard from HL7. This provides the means for a Brand Owner to

 © 2015 GS1 AISBL

register data directly from an internal application, such as an ERP, to the GUDID. The Brand Owner must convert their internal data record into the HL7 SPL standard.

3. GDSN certified Data Pools can register data on behalf of the Brand Owners using the HL7 Structured Product Labelling (SPL) standard. The Brand Owner will need to list their GDSN Data Pool as their Third Party Data Provider when they create their "Labeler" profile with the FDA. The information is entered into the Data Source's normal GDSN upload or registration interface and marked as applicable to be sent to the FDA GUDID. Their GDSN Data Pool would map the appropriate information from the GDSN message into FDA GUDID format and submit on behalf of the data source. The GDSN message would also be published to any other data recipients through GDSN as identified via normal the GDSN process. GS1 successfully tested this capability with 8 Brand Owners with the support of 1Worldsync and GHX in 2012 during the FDA's user acceptance testing. This option is being utilised by many Brand Owners today.

Figure 2-1



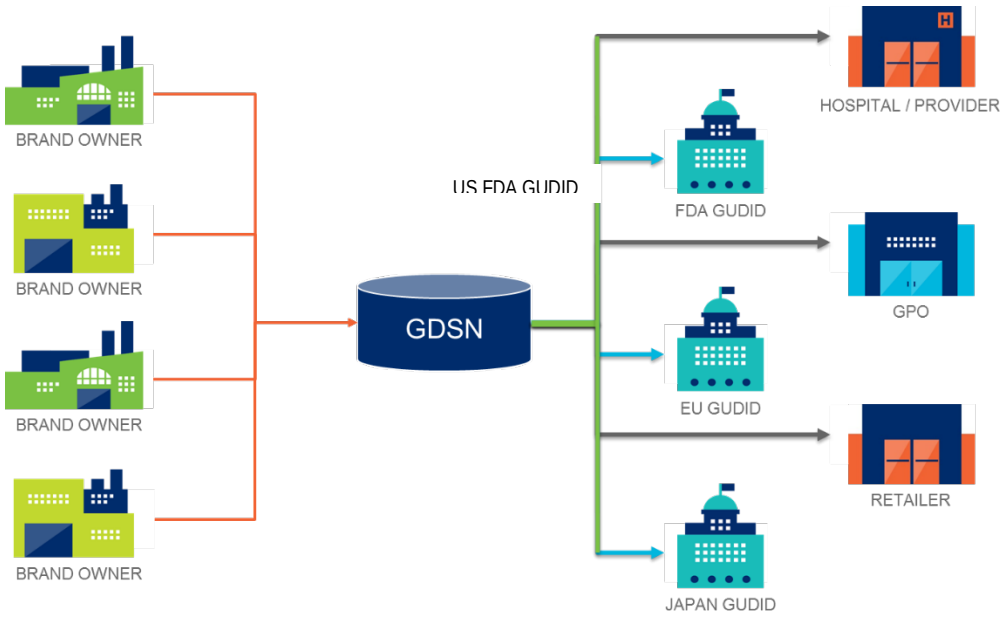
For additional information and supporting information refer to the U.S. FDA GUDID website http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/default.htm

The GDSN is an Internet-based, interconnected, network of interoperable data pools and a Global Registry, the GS1 Global Registry® that enables companies around the world to exchange accurate, standardised and synchronised supply chain data with their trading partners. The Global Data Synchronisation Network (GDSN) enables Brand Owners, distributors and providers to share accurate product information electronically. In addition to receiving the initial product data, the customer can receive product update notifications automatically from the supplier.

The GDSN is an attractive option for Brand Owners who also need to provide product master data to providers, GPOs and distributors since it allows them to provide the right data to the right party with a single connection, as illustrated below.

 © 2015 GS1 AISBL

Figure 2-2



Regulators are working together via the International Medical Device Regulators Forum (IMDRF) to align as much of their requirements as possible. However, each regulator will probably have a specific and distinct set of data requirements. This means that Brand Owners will need to maintain separate data records for each UDI regulator's database. Additionally, they will need to establish separate connections, or methods, of registering their product data in the particular UDI database. The GDSN provides a means for any Brand Owner of any size, to provide data to all UDI databases and their customers (hospitals, distributors, wholesalers, GPOs) simultaneously, with a single connection.

Below are the high-level steps of the data flow from the Brand Owner to the GUDID when using a GDSN Data Pool.

1. The Brand Owner prepares data required by the U.S. FDA's Global UDI Database
2. The Brand Owner provides GUDID data to their GDSN Source Data Pool of choice
3. The GDSN Source Data Pool converts the data provided by the Brand Owner to the HL7 SPL format (refer to the GUDID User Manual for information)
4. The GDSN Source Data Pool registers the Brand Owner's product data using the HL7 SPL format in the GUDID
5. The GDSN Source Data Pool confirms the registration with the Brand Owner, once a confirmation from the GUDID is received by the GDSN Source Data Pool.

GDSN Data Pools offer a secure and easy way for Brand Owners to register their product data with any UDI database, anywhere in the world, via a single connection. From a GDSN point of view, this type of service is classified as an "Out of Network" service, since the data flow described above is different from the GDSN message choreography. This also means that it is not regulated by the Global Registry Access and License Agreement (GRALA) nor covered by the GDSN Certification Criteria. Refer to the GDSN website for more information in and out of network services and a list of GDSN certified Data Pools *http://www.gs1.org/gdsn*

3 GUDID Data Requirements

The Device Identifier (DI) is the primary key in the UDI database and will be linked to other product data elements. Brand Owners will be responsible for submitting and maintaining their own data in the database The U.S. FDA Global UDI Database (GUDID) will not contain the Production Identifiers, i.e. Expiration Date, Batch/Lot Number, Serial Number or others.

© 2015 GS1 AISBL

> *"The core elements are the minimum elements needed to identify a medical device through distribution and use. Regional or National UDID may contain additional elements; however, these additional elements should be kept to a minimum"* – International Medical Device Regulators Forum (IMDRF), UDI System for Medical Devices

The Global Unique Device Identification Database (GUDID) has a set of attributes for population of information about a medical device. These attributes are of various types (Boolean, Code List, Text, etc.) and if it is "Required" or "Not Required". The specifics of each attribute varies based upon the information requested by the attribute's definition and the type of device being described.

The table below provides a list of the GUDID attributes and their particulars as current at the time of the creation of this document as provided by the FDA GUDID Guidance documents. While every effort is made to keep this document up to date, the official list of attributes and particulars is the responsibility and jurisdiction of the FDA. A website link to the official list is provided in the reference section of this document. Users of this document are encouraged to review and become familiar with the official list of attributes and particulars as listed on the FDA's websites. The table uses the headers as defined below.

Figure 3.1- FDA GUDID Table legend

Header	Definition
Data Element	The name of the element being requested.
Description	Text defining the element.
Data Entry Notes	How the is entry to be accomplished. The primary focus of the guidance is primarily written with a web interface user in mind. For a machine to machine user, the notes will have different meaning and be described in the guidance later in this document.
Edit (Editing of entered data is allowed) Rules after Grace Period	Once published on the FDA GUDID public facing website for the first time, the user will have a 7-day grace period within which changes can be made. This field states what editing can be accomplished after the grace period expires.
Required in Database?	Is this data element required to be populated by the FDA? 0 in the first position signifies not required, 1 in the first position signifies required, * after 2 periods signifies multiple occurrences/repeatability, and a number after 2 periods signifies single occurrence/non-repeatability
Data Type & Length	The type of value for the element (Boolean, Text, Code List, etc.) including how many characters are available for population.
Entry List of Values (LOV)	This is a list of values which can be provided for code list attributes
New DI Trigger?	Indicator signifying if a change to this data element would trigger a new Device Identifier to be created. In GS1 Standards, this indicates if a new GTIN should be created due to a change in the value for this element.
Public/ Private Status	Indicator signifying if this element will be posted on the FDA GUDID public facing website (PUBLIC) or for FDA consumption only (PRIVATE)

Document reference:

- The FDA term GS1 14-digit numeric value is equal to a GTIN.
- The FDA term "Primary DI" in GS1-speak would be the primary device GTIN or the EACH level of the hierarchy. For example a DI 101 is the Primary GTIN and DIs 201 and 301 would be the packaging levels such as Pack or Case.

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Device Information								
Device Identifier (DI) Information								
Issuing Agency	Organization accredited by FDA to operate a system for the issuance of UDIs.	Choose a value from the drop down LOV.	None (NO edit, add, or delete are allowed)	Required	NA	GS1; HIBCC; ICCBBA	YES	Public
Primary DI Number	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest package level of a medical device containing a full UDI. For medical devices without packaging, the primary DI number and full UDI may be on the device itself.	Enter the Device Identifier (DI) Number. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters	None (NO edit, add, or delete are allowed)	Required	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.	N/A	YES	Public
Device Count	Number of medical devices in the base package.	Enter the number of devices. Example: Base Package = Box of 100 gloves; Primary DI = 101; Device Count = 100.	None (NO edit, add, or delete are allowed)	Required	Type: Num. Length: 7	N/A	YES	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Unit of Use DI Number	An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.	Enter the Unit of Use DI Number. Must be from same Issuing Agency as Primary DI Unit of Use DI is an identifier used by hospital staff and Materials Management to account for a single device when the UDI is labeled on a higher level of packaging. The Unit of Use DI does not appear on the label. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters If Device Count = 1, cannot add Unit of Use DI Number.	Edit (Editing of entered data is allowed)	Conditionally Required* *If Device Count >1.	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.	N/A	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Labeler DUNS Number	Business number issued by Dun & Bradstreet (D&B) that is used to associate the Labeler (Company) name and address to a given version of model of a device in GUDID.	"Choose appropriate DUNS Number from drop down LOV. To ensure data consistency for the GUDID, DUNS number submitted to the GUDID should associate to the company name that appears on the device label; ideally the address associated with the DUNS number should also match the address on the device label, but since address is not displayed to the GUDID public user, this is not a requirement for data consistency. All edits to information connected to the Labeler DUNS Number must be done through Dun & Bradstreet. No edits of DUNS information will be permitted in the GUDID. "	Edit (Editing of entered data is allowed)* *Other Labeler DUNS listed to your GUDID account can be selected. No Edit (Editing of entered data is allowed)s of DUNS info will be permitted.	Required	NA	Labeler DUNS LOV	NO	Private

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Company Name	Company name associated with the labeler DUNS Number entered in the DI Record.	Auto populated based on the Labeler DUNS Number The labeler company name submitted to the GUDID should match the company name on the device label.	NA (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)	Auto Populated	NA	NA	N/A	Public
Company Physical Address	Company physical address associated with the labeler DUNS Number entered in the DI Record.	Auto populated based on the Labeler DUNS Number Ideally, this address should match the labeler address as shown on the device label but since this data element is not be displayed to the GUDID public user, this is not a requirement for data consistency.	NA (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)	Auto Populated	NA	NA	N/A	Private

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Brand Name	The Proprietary/Trade/Brand name of the medical device as used in device labeling or in the catalog. This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. The brand name is the name that is typically registered with USPTO and have the ® and/or ™ symbol.	Enter the Brand Name. Only symbols ® and ™ will be supported for the current production release of GUDID. NOTE: per Edit Rules, you will not be able to change ® or ™ (if entered) after the Grace Period. Enter NA if the device does not have a Brand Name.	None (NO edit, add, or delete are allowed)	Required	Type: Alphanum. Length: 80	NA	YES	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Version or Model	The version or model found on the device label or accompanying packaging used to identify a category or design of a device. The version or model identifies all devices that have specifications, performance, size, and composition within limits set by the labeler.	Enter the Version or Model. Version/Model can be any distinguishing string of letters and/or numbers. Catalog Number can be entered if device does not currently have a Version or Model. If the device does not have a version, model or catalog number, enter a concept that can be used to identify all devices that have specifications, performance, size, and composition within limits set by the labeler.	None (NO edit, add, or delete are allowed)	Required	Type: Alphanum. Length: 40	NA	YES	Public
Catalog Number	The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.	Enter the Catalog or Reference Number. Catalog/Reference number can also serve as Version/Model if it represents the devices that have specifications, performance, size, and composition within limits set by the labeler.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Optional	Type: Alphanum. Length: 40	NA	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Device Description	Additional relevant information about the device that is not already captured as a distinct GUDID data attribute.	Enter device description. Device description should include any description found on the device label to support user comparison of the device label to the GUDID device record. Otherwise, include any additional description or text found in the device labeling.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Optional	Type: Alphanum. Length: 2000	NA	NO	Public
Commercial Distribution								
DI Record Publish Date	Indicates the date the DI Record is published and available via Public Search.	Choose date from calendar or manually enter date in new format (yyyy-mm-dd). This date determines the Grace Period; the 7 calendar days start the day after the DI Record Publish Date. This date should be set in the future to allow time to ensure accurate data entry. We recommend you set this date in the future, but 7 days prior to any compliance deadline.	None (NO edit, add, or delete are allowed)	Required	Type: Num. (date format) Length: 10	NA	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Commercial Distribution End Date	Indicates the date the device is no longer held or offered for sale. See 21 CFR 807.3(b) for exceptions. The device may or may not still be available for purchase in the marketplace.	Choose date from calendar or manually enter date in new format (yyyy-mm-dd).	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Optional	Type: Num. (date format) Length: 10	NA	NO	Public
Commercial Distribution Status	Indicates whether the device is in commercial distribution as defined under 21 CFR 807.3(b).	Auto populated based on Commercial Distribution End Date. If no Commercial Distribution End Date is entered, the status is 'In Commercial Distribution'	NA (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)	Auto Populated	NA	In Commercial Distribution; Not in Commercial Distribution	NO	Public
Alternative or Additional Identifiers								
Direct Marking (DM) Direct Marking (DM) data elements only apply to devices subject to 21 CFR 801.45.								

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Device Subject to Direct Marking (DM), but Exempt	The device is exempt from Direct Marking requirements under 21 CFR 801.45.	Select checkbox if appropriate. Labeler should select the checkbox “Device Subject to Direct Marking (DM), but Exempt” only if the device: (1) is intended to be used more than once and (2) is intended to be reprocessed before each use, but also (3) meets any one of the exception criteria outlined under 21 CFR 801.45(d). If the device is not required to be directly marked under 21 CFR 801.45(a), then this box should not be checked.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Conditionally Required* *If device is subject to 801.45	Type: Boolean	NA	NO	Public
DM DI Different from Primary DI	Indicates that the DM DI Number is different than the Primary DI Number.	Select checkbox if appropriate.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Conditionally Required* *If device is subject to 801.45	Type: Boolean	NA	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
DM DI Number	An identifier that is marked directly on the medical device and is different than the Primary DI Number; only applicable to devices subject to Direct Marking requirements under 21 CFR 801.45.	Enter Direct Marking DI Number. Must be from same Issuing Agency as Primary DI. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Conditionally Required* *If device subject to 801.45 and 'DM DI Different from Primary DI' is checked	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.	NA	NO	Public
Secondary DI								
Issuing Agency of Secondary DI	Name of Secondary DI Issuing agency.	Choose a value from the drop down LOV.	None (NO edit, add, or delete are allowed)	Optional	NA	GS1; HIBCC; ICCBBA; NDC/NHRIC	NO	Public

© 2015 GS1 AISBL

Secondary DI Number	Enter Secondary DI Number. If your product is labeled with a UDI and barcode from more than one issuing agency (for regulatory or marketing reasons), you must choose one issuing agency system as the Primary DI and enter the other issuing agency information here, as a Secondary DI. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters	None (NO edit, add, or delete are allowed)	Optional	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.	NA	Enter Secondary DI Number. If your product is labeled with a UDI and barcode from more than one issuing agency (for regulatory or marketing reasons), you must choose one issuing agency system as the Primary DI and enter the other issuing agency information here, as a Secondary DI. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric,	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
						with 10 or 16 characters		
Package DI	Every device package shall bear a UDI, 21 CFR 801.20(a) (2). Package DIs do not need their own DI record; instead package information should be entered in the Package DI section of the Primary DI record for that device. According to 21 CFR 801.3, a package is defined as a fixed quantity of a particular version or model of a device.							

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Package DI Number	A device identifier for the package configuration that contains multiple units of the base package (does not include shipping containers).	Enter Package DI Number. Must be from same Issuing Agency as Primary DI. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters Examples: Box of Gloves = DI 101 4 Boxes of Gloves (DI 101) in a Carton = Package DI 201 (the UDI on the Carton) 5 Cartons (Pkg DI 201) in a Case = Package DI 301 (the UDI on the Case) 10 Boxes of Gloves (DI 101) in a Carton = Package DI 202 (the UDI on the Carton).	Add (Addition of new data is allowed)	Conditionally Required* *If device is available in higher levels of packaging	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.	NA	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Quantity per Package	The number of packages with the same Primary DI or Package DI within a given packaging configuration.	Enter the number of devices per package. The quantity of a package configuration must be >1. Examples: Package – Carton, Pkg DI 201 contains 4 boxes of DI 101; the quantity per package is 4. Package – Case, Pkg DI 301 contains 5 cartons of Pkg DI 201; the quantity per package is 5. Package – Carton, Pkg DI 202 contains 10 boxes of DI 101; the quantity per package is 10.	Add (Addition of new data is allowed)	Conditionally Required* *If Package DI is entered	Type: Num. Length: 9	NA	NO	Public
Contains DI Package	The Primary DI for the base package or the Package DI for any lower level package configuration contained within a given package configuration.	Choose a value from the drop down LOV. Examples: Package DI 201 (Carton) contains base package DI 101. Package DI 202 (Carton) contains base package DI 101. Package DI 301 contains lower level Package DI 201 (Carton).	Add (Addition of new data is allowed)	Conditionally Required* *If Package DI is entered	NA	DI numbers; base package and all lower levels of packaging	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Package Type	Text to describe the outer packaging of the product and enables users to understand higher level packaging configurations.	Enter name or description of package. This field is free text. There is no implied definition or standard quantity to any package name.	Add (Addition of new data is allowed)	Optional	Type: Alphanum. Length: 20	NA	NO	Private
Package Discontinue Date	Indicates the date this particular package configuration is discontinued by the labeler.	Choose date from calendar or manually enter in format (yyyy-mm-dd). Discontinuation of a package is directly related to the discontinuation of the primary DI of the base package. However, a package can also be discontinued without the discontinuation of the base package.	Add (Addition of new data is allowed)	Conditionally Required* *If Package DI Number and Commercial Distribution End Date are entered, must also enter Package Discontinue Date	Type: Num. (date format) Length: 10	NA	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Package Status	Indicates whether the package is in commercial distribution as defined under 21 CFR 807.3(b).	Auto populated based on Package Discontinue Date. If Package DI and related elements are entered and no Package Distribution End Date is entered, the status is 'In Commercial Distribution.'	NA (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)	Auto Populated	NA	In Commercial Distribution; Not in Commercial Distribution	NO	Public
Customer Contact								
Customer Contact Phone	Phone number for the support contact. SPL Definition: "Phone number for the Customer contact; to be used by patients and consumers for device-related questions."	Enter 10 digit North American number. For international numbers, start with "+" Does not require the use of () or -, but can enter these symbols.	Can edit, add, or delete after Grace Period.	1..* Required if support contact information is entered SPL Text: "1..1 Conditionally Required* *ONLY required if Customer Contact Phone is entered	Numeric, 20 (10) SPL Text: "Alphanumeric"	N/A	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Customer Contact Email	Email for the Customer contact; to be used by patients and consumers for device-related questions.	Enter email address. This email address could be the same one that appears on the device labeling or the company website. Labelers can identify a Customer Contact email and a Customer Contact phone number for each device record. If a phone number is entered and you don't have a Customer Contact email, please enter 'xx@xx.xx'	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Conditionally Required* *ONLY required if Customer Contact Email is entered	Type: Alphanum. Length: 100	NA	NO	Public
Device Status								

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)	Indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3.	Select checkbox if DI record is for a product defined under 21 CFR 1271.3 If checked, the labeler must assign and label each HCT/P device with a distinct identification code, per 21 CFR 1271.290(c). The distinct identification code may take the form of a Donation Identification Number (DIN) , serial number, lot number, or a combination of these production identifiers (PIs). Labelers of HCT/Ps regulated as medical devices should select the appropriate type of PI that appears on the label of the device.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Optional If no data is provided, 'No' is stored	Type: Boolean	NA	NO	Public
Kit	Indicates that the device is a convenience, combination, in vitro diagnostic (IVD), or medical procedure kit. Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and is being distributed as a medical device.	Select checkbox if DI record is for a kit. Do not check if the device is a constituent part of a kit.	None (NO edit, add, or delete are allowed)	Optional If no data is provided, 'No' is stored	Type: Boolean	NA	YES	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Combination Product	Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity; packaged together as a single package; or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the products in the combination product must be a device in this case.	Select checkbox if DI record is for a combination product. Do not check if the device is a constituent part of a combination product.	None (NO edit, add, or delete are allowed)	Optional If no data is provided, 'No' is stored	Type: Boolean	NA	YES	Public
Premarket								
Device Exempt from Premarket Submission	Device is exempt from FDA Premarket regulations; or a preamendment device. SPL Definition: "FDA Premarket submission is not required for this device."	Select checkbox if FDA has by regulation exempted this device from premarket submission requirements; or for preamendment devices that are not subject to premarket submission requirements. If left unselected, a 'No' is stored and a Premarket Submission Number should be entered below.	None (NO edit, add, or delete are allowed)	Conditionally Required* *Premarket Submission Number OR exempt status fulfills regulatory requirement.	Type: Boolean	NA	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
FDA Premarket Submission Number	Number associated with the regulatory decision regarding the applicant's legal right to market a medical device for the following submission types: 510(k), PMA, PDP, HDE, BLA, and NDA.	Enter current FDA Premarket Submission Number(s). Each DI record represents a version or model of a device. For each DI record, you must submit the original premarket authorization number and the supplement number through which you obtained approval or clearance for the version or model identified in the DI record, as required by 830.310(b)(11). FDA Premarket Numbers should be verified with the FDA PMA or 510(k) database to make sure the Number represents the subject of the device record. Device records should be updated with additional numbers in the future, as needed. Example: PMA #123456 should be entered as 'P123456.'	Add (Addition of new data is allowed)	Conditionally Required* *Premarket Submission Number OR exempt status fulfills regulatory requirement.	Type: Alphanum. Length: 8	NA	NO	Public

© 2015 GS1 AISBL

Supplement Number	Number assigned by FDA to a supplemental application for approval of a change in a medical device with an approved PMA, HDE, or PDP.	Enter all valid Supplement Numbers. Each DI record represents a version or model of a device. For each DI record, you must submit the original premarket authorization number and the supplement number through which you obtained approval for the version or model identified in that DI record, as required by 830.310(b)(11). Although not all PMA supplements are applicable to a given model or version, if FDA approves a subsequent supplement applicable to that version or model, the GUDID DI record must be updated with that supplement number, in accordance with 21 CFR 830.330(b). 30 day notice supplements should be submitted ONLY if the 30 day notice impacts the device design specifications, or performance of the finished devices. Do not enter alpha	Add (Addition of new data is allowed)	Conditionally Required* *Premarket Submission Number OR exempt status fulfills regulatory requirement.	Type: Num. Length = CDRH 1-3 digits, CBER 1-4 digits	NA	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
		characters. Example: Supplement 4 should be entered as 004.						
FDA Product Code								
Product Code	Classification for devices issued by the FDA.	Enter all applicable Product Codes, three-letter code. For all PMA and 510k devices, Product Codes are assigned in the FDA approval or clearance letter, respectively. For Class I and exempt devices, the device Product Code may be self-identified.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Conditionally Required* *Unless device is a kit or IVD with a BL premarket submission number	Type: Alpha Length: 3	FDA Product Code list	NO	Public
Product Code Name	Name associated with the three-letter Product Code.	Auto populated based on 3-letter Product Code	NA (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)	Auto Populated	NA	NA	NO	Public
FDA Listing								

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
FDA Listing Number	Number assigned by FDA during Registration and Listing to all devices in commercial distribution, regardless of pre-market authorization requirements per 21 CFR 807.28(f).	Enter all relevant listing numbers that enable the labeler to commercially distribute the given version or model of device. Listing number is optional for HCT/P devices, Kits and IVDs with a BLA premarket number.	Add (Addition of new data is allowed)	Conditionally Required* *Unless device is an HCT/P, kit or IVD with a BL premarket submission number	Type: Alphanum. Length: 7	NA	NO	Private
GMDN								

© 2015 GS1 AISBL

Code SPL Name - GMDN Preferred Term Code FDA Preferred Term Code	GMDN Preferred Term (PT) Code is a unique five-digit code used to identify common device types. This PT Code is assigned to medical devices and related health care products for the purposes of grouping and categorization. SPL Definition: “Unique numerical five-digit number used to generically identify medical devices and related health care products."	Enter all applicable GMDN Preferred Term Codes or FDA PT Codes. Each device record must have at least one assigned GMDN Code/FDA PT Code; DI records are allowed >1 GMDN Code/FDA PT Code, if necessary. Must enter GMDN Code OR FDA PT Code, please don't enter both codes for the same GMDN Name and Definition. For GMDN Codes: Enter only the 5-digit number, omit the 'P' For FDA PT Codes: Enter the 4-letter code. The FDA PT Codes are assigned to each GMDN term, used in place of a GMDN Code. They enable labelers to assign a GMDN term to their GUDID submission until a GMDN Code can be obtained from the GMDN Agency. The FDA PT Codes can be found in the Find FDA PT Code Module on the GUDID website. For more information, see the GUDID Final Guidance.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Required	Type: Num. Length: 5	NA	NO	Private

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
		The FDA PT Codes can be found in the Find FDA PT Code Module on the GUDID website.						
SPL Name - FDA Preferred Term Code	SPL Text: "Unique four-character value assigned by the FDA to indicate a GMDN Preferred Term without exposing the GMDN PT Code."			SPL Text: "1..* Required - either GMDN PT Code or FDA PT Code"	SPL Text: "Alpha, 4"	SPL Text: "FDA DB"		
Name	Name of the common device type associated with the GMDN Preferred Term Code/FDA PT Code.	Auto populated based on GMDN Preferred Term Code/FDA PT Code.	NA (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)	Auto Populated	NA	NA	NO	Public
Definition	Definition of the common device type associated with the GMDN Preferred Term Code/FDA PT Code.	Auto populated based on GMDN Preferred Term Code/FDA PT Code.	NA (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)	Auto Populated	NA	NA	NO	Public
Device Characteristics								
For Single-Use	Choose Yes/No from the drop down list.	None (NO edit, add, or delete are allowed)	Required	Type: Boolean	Choose Yes/No from the drop down list.	Yes/No	YES	Public
Production Identifier(s) in UDI								

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Lot or Batch Number	Indicates the device is managed by lot or batch number. This number can be found on the device label or packaging. Lot or Batch means one finished device or more that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.	Choose Yes/No from the drop down list. For stand-alone software, select Yes to indicate that the software version number will be represented as a Lot or Batch number	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Required	Type: Boolean	Yes/No	NO	Public
Manufacturing Date	Indicates the device is managed by date of manufacture; the date a specific device was manufactured.	Choose Yes/No from the drop down list.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Required	Type: Boolean	Yes/No	NO	Public
Serial Number	Indicates the device is managed by serial number. This number can be found on the device label or packaging. The serial number is assigned by the labeler and should be specific to each device.	Choose Yes/No from the drop down list.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Required	Type: Boolean	Yes/No	NO	Public
Expiration Date	Indicates the device is managed by expiration date; the date by which the label of a device states that the device must or should be used.	Choose Yes/No from the drop down list.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Required	Type: Boolean	Yes/No	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Donation Identification Number	Indicates the device is managed by a Donation Identification Number. This number can be found on the device label or packaging. The Donation Identification Number is applicable to devices that are also regulated as HCT/Ps and is a number that is assigned to each donation.	Choose Yes/No from the drop down list. This PI is only applicable to HCT/P products regulated as medical devices.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Required	Type: Boolean	Yes/No	NO	
Latex Information								
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)	Indicates that the device or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437. Choosing 'Yes' indicates that the device label or packaging contains one of the following statements: (1) "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions", (2) This Product Contains Dry Natural Rubber", (3) Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions" or (4) "The Packaging of This Product Contains Dry Natural Rubber".	Choose Yes/No from the drop down list.	None (NO edit, add, or delete are allowed)	Required	Type: Boolean	Yes/No	YES	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Device labeled as "Not made with natural rubber latex"	Indicates that natural rubber latex was not used as materials in the manufacture of the medical product and container and the device labeling contains this information. Only applicable to devices not subject to the requirements under 21 CFR 801.437. Not all medical products that are NOT made with natural rubber latex will be marked.	Select checkbox if appropriate. Only applicable if the response to "Device required to be labeled as containing natural rubber latex or dry natural rubber" is "No". Optional element for labelers who include a statement of 'latex-free' on their label or in their labeling. FDA finds these statements: 'latex-free' and 'does not contain latex', to be not scientifically supportable and strongly recommends they not be used in medical product labeling. Instead FDA recommends the use of the statement 'Not made with natural rubber latex." It is not assumed that all devices NOT made with natural rubber latex are marked; therefore this is an optional element for the labelers who choose to make a statement in the labeling.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Optional If no data is provided, "No" is stored	Type: Boolean	NA	NO	Public

© 2015 GS1 AISBL

Data Element	Description	Data Entry Notes	Edit (Editing of entered data is allowed) Rules after Grace Period	Required	Data Type & Length	Entry List of Values (LOV)	New DI Trigger ?	Public/ Private Status
Prescription Status								
Prescription Use (Rx)	Indicates that the device requires a prescription to use.	Select checkbox if appropriate. Can select both Rx and OTC for one DI record.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Optional If no data is provided, "No" is stored	Type: Boolean	NA	NO	Public
Over the Counter (OTC)	Indicates that the device does not require a prescription to use and can be purchased over the counter (OTC).	Select checkbox if appropriate. Can select both Rx and OTC for one DI record.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Optional If no data is provided, "No" is stored	Type: Boolean	NA	NO	Public
MRI Safety Status								
What MRI safety information does the labeling contain?	Indicates the MRI Safety Information, if any, that is present in the device labeling. Please see the ASTM F2503-13 standard for more information.	Choose a value from the drop down LOV. The final rule does not require MRI-compatibility testing; it only requires submission of information regarding MRI-compatibility that the labeler already possesses.	Edit (Editing of entered data is allowed)* *ONLY if changing from 'Labeling does not contain…' to other MR status (Safe, Unsafe, Conditional (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)l). Otherwise, NO changes are allowed.	Required	NA	MR Safe, MR Unsafe, MR Conditional, Labeling does not contain MRI Safety information	NO	Public

© 2015 GS1 AISBL

Clinically Relevant Size								
Size Type	Dimension type for the clinically relevant measurement of the medical device.	Choose a value from the drop down LOV. If the desired Size Type is not in the current list, select 'Size Text, specify' and the data element 'Size Type Text' will appear (see below). It is expected that the 'Size Text, specify' will only be available for a limited time. Use this option to help us build a list of values that are appropriate for your device type. GUDID reserves the right to review all suggestions before adding values to the Size Type LOV. More than one Size Value per Type and more than one Size Type may be added to each DI record.	Add (Addition of new data is allowed)	Conditionally Required* *If device is available in more than one size	NA	Circumference; Depth; Device Size Text, specify; Catheter Gauge ; Outer Diameter; Height; Length; Lumen/Inner Diameter; Needle Gauge; Total Volume; Width; Weight; Pressure; Pore Size; Area/Surface Area; Angle	NO	Public
Size Value	Numeric value for the clinically relevant size measurement of the medical device.	Enter numeric value for size. Decimals are accepted; fractions are not accepted. Each Size Value should be entered separately. GUDID is not accepting Size Value as a range at this time.	Add (Addition of new data is allowed)	Conditionally Required* *Required if device is available in more than one size	Type: Num. Length: 40	NA	NO	Public

© 2015 GS1 AISBL

Size Unit of Measure	"The unit of measure associated with each clinically relevant size. SPL Text: "The unit of measure associated with each clinically relevant size. The unit of measure must conform to UCUM standards."	Choose a value from the drop down.	Add (Addition of new data is allowed)	Conditionally Required* *Required if device is available in more than one size	NA	For length: Centimeter; Decimeter; Feet; Femtometer; Inch; Kilometer; Meter; Micrometer; Millimeter; Nanometer; Picometer; Yard; For area: Square centimeter; Square foot; Square inch; Square meter; Square millimeter For weight: Gram; Kilogram; Microgram; Milligram; Metric Ton; Pound; Ton For total volume: Centiliter; Cubic Inch; Cup; Deciliter; Femtoliter; Fluid Ounce; Gallon; Kiloliter; Liter; Microliter; Milliliter; Nanoliter; Picoliter;	NO	Public

© 2015 GS1 AISBL

Clinically Relevant Size								
						Pint; Quart For gauge: French; Gauge For angle: Degree For pressure: Pound per Square Inch; millibar; KiloPascal; Units per Liter; Hertz; Millibar		
Size Type Text SPL Name: "Size Text"	Additional undefined device size not represented in the GUDID Size Type LOV.	Enter Size Type, Size Unit and Unit of Measure for each entry.	Add (Addition of new data is allowed)	Conditionally Required* *Required if 'Size Text, specify' is selected above	Type: Alphanum. Length: 200	NA	NO	Public
Storage and Handling								

© 2015 GS1 AISBL

Clinically Relevant Size								
Storage and Handling Type	"Indicates storage and handling requirements that are required for the device including temperature, humidity, and atmospheric pressure. SPL Definition: "Indicates storage requirements are required for the device, including: temperature, humidity, etc."	Choose a value from the drop down LOV. Conditions of the Storage and Handling Type are measured below as a range, with a Low Value and a High Value. More than one Storage and Handling Type can be added per device record.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Optional	NA	Handling Environment Atmospheric Pressure; Handling Environment Humidity; Handling Environment Temperature; Special Storage Conditions; Storage Environment Atmospheric Pressure; Storage Environment Humidity; Storage Environment Temperature	NO	Public

© 2015 GS1 AISBL

Clinically Relevant Size								
Low Value SPL Name: "Storage and Handling Low Value"	"Indicates the low value for storage and handling requirements. SPL Definition: "Indicates the low value for storage requirements, such as temperature, humidity, etc"	Enter a number for Low Value. Must enter at least one value, Low or High but can enter both Low Value and High Value, if needed. When Storage and Handling value is a range, this is the lower end of that range When Storage and Handling value is less than a value, enter the number here. When Storage and Handling value is exactly a value, enter the value here and in Storage and Handling High Value	Can edit, add, or delete after Grace Period.	00..* A Low Value and/or a High Value is required if Storage and Handling is provided. SPL Text: "0..1 Conditionally Required* *One value (Low or High) is required if Storage and Handling Type is added to the device record."	Numeric, 6	N/A	NO	Public

© 2015 GS1 AISBL

Clinically Relevant Size								
High Value SPL Name: "Storage and Handling High Value"	"Indicates the high value for storage and handling requirements. SPL Definition: "Indicates the high value for storage requirements, such as temperature, humidity, etc"	Enter a number for High Value. Must enter at least one value, Low or High but can enter both Low Value and High Value, if needed. When Storage and Handling value is a range, this is the higher end of that range. When Storage and Handling value is greater than a value, enter the number here. When Storage and Handling value is exactly a value, enter the value here and in Storage and Handling Low Value.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Conditionally Required* *One value (Low or High) is required if Storage and Handling Type is added to the device record	Type: Num. Length: 6	NA	NO	Public
Unit of Measure SPL Name: "Storage and Handling Unit of Measure"	The unit of measure associated with the storage and handling conditions. SPL Text: "The unit of measure associated with the storage and handling conditions. "The unit of measure associated with the storage and handling conditions. The unit of measure associated with the storage and handling conditions.	Choose a value from the drop down LOV.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Conditionally Required* *Required if Storage and Handling Type is added to the device record	NA	Degrees Celsius; Degrees Fahrenheit; Degrees Kelvin; Kilo Pascal; Percent (%) Relative Humidity, Millibar	NO	Public

© 2015 GS1 AISBL

Clinically Relevant Size								
Special Storage Conditions	"Indicates any special storage requirements for the device. SPL Text: "Indicates any special storage requirements for the product."	Enter any other storage conditions. For devices kept at room temperature, or other standard conditions, input that information here.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Conditionally Required* *Required if 'Special Storage Conditions' is selected above	Type: Alphanum. Length: 200	NA	NO	Public
Sterilization Method								
Device Packaged as Sterile	Indicates the medical device is free from viable microorganisms. See ISO/TS 11139.	Choose Yes/No from the drop down list. The two Sterilization Method questions are independent of each other; this element is designed to capture information about the device as it enters Commercial Distribution. These data elements are not designed to capture sterilization procedures executed by the manufacturer or labeler.	None (NO edit, add, or delete are allowed)	Required	Type: Boolean	Yes/No	YES	Public

© 2015 GS1 AISBL

Clinically Relevant Size								
Requires Sterilization Prior to Use	Indicates that the device requires sterilization prior to use.	Choose Yes/No from the drop down list. The two Sterilization Method questions are independent of each other; this element is designed to capture information about the device before it can safely encounter a patient, regardless of whether the device is single use or reused after reprocessing. These data elements are not designed to capture sterilization procedures executed by the manufacturer or labeler. If answered 'Yes', at least one Sterilization Method (below) must be selected.	None (NO edit, add, or delete are allowed)	Required	Type: Boolean	Yes/No	YES	Public

© 2015 GS1 AISBL

Clinically Relevant Size								
Sterilization Method	Indicates the method(s) of sterilization that can be used for this device.	Choose a value from the drop down LOV. Only applicable if the answer to 'Requires Sterilization Prior to Use' is 'Yes'; otherwise, the LOV will remain inactive. The Entry LOVs represent the sterilization methods recognized by the CDRH Infection Control Branch. Methods selected should be only those approved for each device by the CDRH Office of Device Evaluation.	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)	Conditionally Required* *if 'Requires Sterilization Prior to Use' is marked 'Yes'	NA	Chlorine Dioxide; Dry Heat; Ethylene Oxide; High Intensity Light or Pulse Light; Hydrogen Peroxide; Microwave Radiation; Moist Heat or Steam; Ozone; Peracetic Acid; Radiation; Sound Waves; Ultraviolet Light	NO	Public

© 2015 GS1 AISBL

4 GS1 GDSN to FDA GUDID Mapping

Population of the FDA GUDID through the use of a GS1 GDSN message and a GDSN Certified Data Pool as a Third Party requires an understanding of the GDSN and its attributes. While many of the FDA GUDID attributes can be mapped one to one with a GS1 GDSN equivalent, there are others that do not map (and are logically populated) or map via more than one GDSN attribute.

The first table below provides a mapping between the FDA GUDID attribute list and the corresponding GS1 GDSN Attribute(s). The attributes listed in the table use the name assigned in the GDSN standards. Each user of this document should consult with their GDSN Certified Data Pool for the exact naming convention and message formatting applicable to the contract between the user and the Data Pool.

The second table below provides a mapping between the FDA GUDID code values and the corresponding GS1 GDSN code values. The values listed in the table use the name assigned in the GDSN standards. Each user of this document should consult with their GDSN Certified Data Pool for the exact naming convention and message formatting applicable to the contract between the user and the Data Pool.

Figure 4.1- GDSN to GUDID Attribute Table legend

Header	Definition
FDA GUDID Data Element	The name of the element being requested.
Module	The name of the higher level grouping of classes and attributes. Modules group together similar attributes or attributes which describe or define certain information.
Content	This is a textual term used to provide a high level grouping of what the row is describing, for example Attribute, Association, etc.
Attribute/ Role	The name of the attribute as listed in the GS1 Global Data Dictionary (GDD) for use with GDSN v3.1.
Datatype/ Secondary Class	The type of value for the element (Boolean, Text, Code List, etc.) including how many characters are available for population. This may also be the name of a class or group attributes to which are referenced for use at this point in the message.
Definition	Text defining the element.
Code List Name	When the attribute is of a Data Type called Code List, there is a specified list of Code Values (Valid Values) from which the attribute must be populated. This is the name of the code list which has the relevant values.
GDSN Notes	Any brief guidance or implementation notes applicable to the row.
GDSN v2.8 Attribute Name	The name of the GDSN v2.8 Attribute from which the row was mapped. This column will assist users as they migrate from GDSN v2.8 to GDSN v3.1

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Device Information							
Device Identifier (DI) Information							
Issuing Agency			-			LOGICAL POPULATION- On the outbound FDA GUDID Message by the Data Pool. Will use the value "GS1" in all GDSN instances.	Data Pool to default on outbound message
Primary DI Number	CoreItem	GTIN (generalization)	GTIN	TradeItemIdentification	Trade Item Identification for a TradeItem.		globalTradeItemNumber
Device Count	AVP		uDIDDeviceCount	Integer	The count of medical devices which are contained inside the base item for regulatory purposes.	Only populated at the lowest level of the hierarchy.	uDIDDeviceCount
N/A	CoreItem	Attribute	componentNumber	nonNegativeInteger	Indicate a sequence number of a component of a trade item.		
Unit of Use DI Number	CoreItem	Attribute	componentIdentification	Identifier (GTIN)	An identifier for a component.		fDAUnitOfUseGTIN
Labeler DUNS Number	AdditionalKeyDataTypes	Attribute	additionalPartyIdentificationTypeCode	Code	Identification of a party by use of a code in addition to the Global Location Number.	Brand owner GLN is a GDSN Mandatory attribute. This pair of attributes will be provided as additional party identification tied specifically to the Brand Owner GLN.	additionalPartyIdentificationType

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Labeler DUNS Number	PartyInRole	Attribute	additionalPartyIdentification	string (Text 1-80 Characters)	Identification of a party by use of a code other than the Global Location Number.		additionalPartyIdentificationValue
Company Name						FDA will populate based on the DUNS and D&B	
Company Physical Address						FDA will populate based on the DUNS and D&B	
Brand Name	TradeItemDescriptionModule	Attribute	brandName	string (Text 1-70 Characters)	The recognizable name used by a brand owner to uniquely identify a line of trade item or services. This is recognizable by the consumer.		brandName
Version or Model	AdditionalKeyDataTypes	Attribute	additionalTradeItemIdentificationTypeCode	Code	This code will be used to cross-reference the Vendors internal trade item number to the GTIN in a one to one relationship.	Use code value of MODEL_NUMBER	additionalTradeItemIdentificationType
Version or Model	GS1IdentificationComponents	Attribute	additionalTradeItemIdentification	AdditionalTradeItemIdentification	Alternative means to the Global Trade Item Number to identify a trade item.		additionalTradeItemIdentificationValue
Catalog Number	AdditionalKeyDataTypes	Attribute	additionalTradeItemIdentificationTypeCode	Code	This code will be used to cross-reference the Vendors internal trade item number to the GTIN in a one to one relationship.	Use code value of SUPPLIER_ASSIGNED	additionalTradeItemIdentificationType
Catalog Number	GS1IdentificationComponents	Attribute	additionalTradeItemIdentification	AdditionalTradeItemIdentification	Alternative means to the Global Trade Item Number to identify a trade item.		additionalTradeItemIdentificationValue

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Device Description	TradeItem DescriptionModule	Attribute	additionalTradeItemDescription	Description500 (Free Text 1-500 Characters) (Language Qualified)	Additional variants necessary to communicate to the industry to help define the product. Multiple variants can be established for each GTIN. This is a repeatable field, e.g. Style, Colour, and Fragrance. Allows for the representation of the same value in different languages but not for multiple values.		additionalTradeItemDescription
Commercial Distribution							
DI Record Publish Date (yyyy-mm-dd)	AVP		uDIDPublishDate	DateTime	The date upon which the Trade Item can be published by the Unique Device Identifier Database (UDID) in their public facing systems. Until this date, the product information may reside in the UDID, but will not be visible to the public. This data is not	This attribute is trading partner dependent. The specific UDID GLN should be provided with the date to ensure the correct date is sent to that UDID.	uDIDPublishDate
Commercial Distribution End Date (yyyy-mm-dd)	DeliveryPurchasingInformationModule	Attribute	lastShipDateTime	DateTime	Indicates the latest date that the trade item can be shipped. This is independent of any specific ship-from location.		lastShipDate

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Commercial Distribution Status						FDA will populate based on the publication date (AVP-fDAGUDIDPublishDate or final deployment attribute-uDIDPublishDate) and the discontinueDate at the GDSN each level.	
Alternative or Additional Identifiers							
Direct Marking (DM)							
Device Subject to Direct Marking (DM), but Exempt	AVP		isTradeItemExemptFromDirectPartMarking	Boolean	Indicator signifying the trade item is exempt from direct identification marking according to regulation or regulatory filings within the target market.	AVP-isTradeItemExemptFromDirectPartMarking	isTradeItemExemptFromDirectPartMarking
DM DI Different from Primary DI			-			LOGICAL POPULATION-(Logical BOOLEAN value of TRUE from the population of a value of DIRECT_PART_MARKING in additionalTradeItemIdentification)	Data Pool to default on outbound message
DM DI Number	AVP		directPartMarking	String	This is a number or marking placed directly on the medical device.	AVP-directPartMarking	directPartMarking
Secondary DI							

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Issuing Agency	AdditionalKeyDataTypes	Attribute	additionalTradeItemIdentificationTypeCode	Code	This code will be used to cross-reference the Vendors internal trade item number to the GTIN in a one to one relationship.		additionalTradeItemIdentificationType
Secondary DI Number	GS1IdentificationComponents	Attribute	additionalTradeItemIdentification	AdditionalTradeItemIdentification	Alternative means to the Global Trade Item Number to identify a trade item.		additionalTradeItemIdentificationValue
Package DI							
Package DI Number	GS1IdentificationComponents	Attribute	gtin	GTIN	Global Trade Item Number (GTIN), the GS1 key used for the identification of trade items.		globalTradeItemNumber (use hierarchy to obtain parent-child information)
N/A	CoreItem	Attribute	quantityOfChildren	nonNegativeInteger	Value indicates the number of unique next lower level trade items contained in a complex trade item. A complex trade item can contain at least 2 different GTINs.		quantityOfChildren
N/A	CoreItem	Attribute	totalQuantityOfNextLowerLevelTradeItem	nonNegativeInteger	This represents the Total quantity of next lower level trade items that this trade item contains.		totalQuantityOfNextLowerLevelTradeItem
Contains DI Package	CoreItem	ChildTradeItem	ChildGTIN (generalization)	gtin	A trade item in the item hierarchy level immediately below the parent trade item.	This is the actual childGTIN for the next lower level.	childGTIN

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Quantity per Package	CoreItem	Attribute	quantityOfNextLowerLevelTradeItem	nonNegativeInteger	The number of one child trade item (as identified by the association of ChildTradeItem class to TradeItemIdentification class) contained by the parent trade item. The child trade item must be in the hierarchy level immediately below the parent trade item.		quantityOfNextLowerLevelTradeItem
N/A	Packaging InformationModule	Attribute	packagingTypeCode	Code	The dominant means used to transport, store, handle or display the trade item as defined by the data source. This packaging is not used to describe any manufacturing process. Data recipients can use this data for: • Space Planning • Data Accuracy (Tolerances) • Supply Chain processes • Recycling process (In combination with packaging materials) • Product buying/procurement decisions • Tax calculations/fees/duties calculation		packagingTypeCode
Package Type						LOGICAL POPULATION- (Logical Population by Data Pools based on the Packaging Type Code value populated.) Only the description is provided to the GUDID	packagingTypeDescription

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Package Discontinue Date	TradeItem SynchronisationDates	Attribute	discontinuedDateTime	DateTime	Communicates the date on which the trade item is no longer to be manufactured.		discontinuedDate
Package Status						FDA will populate based on the publication date (AVP-fDAGUDIDPublishDate or final deployment attribute-uDIDPublishDate) and the discontinueDate for each package level published. In GDSN these will be the inner pack, case and pallet levels as applicable.	
Customer Contact							
N/A	TradeItem ContactInformation	Attribute	contactTypeCode	Code	The general category of the contact party for a trade item for example Purchasing.	Value populated for the contact information is the CONSUMER_SUPPORT	contactType
Customer Contact Phone	CommunicationChannel	Attribute	communicationChannelCode	Code	Code specifying the type of communication channel, for example TELEPHONE.	Value populated for the support contact phone number is TELEPHONE	communicationChannelCode

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Customer Contact Phone	CommunicationChannel	Attribute	communicationValue	string (Text 1-200 Characters)	Text identifying the endpoint for the communication channel, for example a telephone number or an e-mail address.		communicationNumber
Customer Contact Email	CommunicationChannel	Attribute	communicationChannelCode	Code	Code specifying the type of communication channel, for example TELEPHONE.	Value populated for the support contact email is EMAIL	communicationChannelCode
Customer Contact Email	CommunicationChannel	Attribute	communicationValue	string (Text 1-200 Characters)	Text identifying the endpoint for the communication channel, for example a telephone number or an e-mail address.		communicationNumber
Device Status							
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)	AVP		doesTradeItemContainHumanTissue	Boolean	The trade item has, as a component or ingredient, human tissue. The amount of tissue is not limited to a certain amount, any amount will cause a flag of TRUE.	AVP-doesTradeItemContainHumanTissue	doesTradeItemContainHumanTissue
Kit	AVP		groupedProduct	Code	Code representing if the trade item is considered by the manufacturer to be more than a single item, such as a kit, combination item.	AVP-groupedProduct (KIT)	groupedProduct
Combination Product	AVP		groupedProduct	Code	Code representing if the trade item is considered by the manufacturer to be more than a single item, such as a kit, combination item.	AVP-groupedProduct (COMBINATION)	groupedProduct

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
(Kit and Combination Product)	AVP		groupedProduct	Code	Code representing if the trade item is considered by the manufacturer to be more than a single item, such as a kit, combination item.	AVP-groupedProduct (KIT_AND_COMBINATION) (Will provide a TRUE value for both KIT and COMBINATION flags)	groupedProduct
Premarket							

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Device Exempt from Premarket Submission	AVP		exemptFromFDAPreMarketAuthorization	Boolean	Device is exempt from FDA Premarket regulations. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act in order to obtain marketing clearance. Please note that some Class III preamendment devices may require a Class III 510(k). See "Historical Background2" for additional information.	AVP-exemptFromFDAPreMarketAuthorization External Code managed by FDA.	exemptFromFDAPreMarketAuthorization
FDA Premarket Submission Number	GDSNTradeItemClassification	Attribute	additionalTradeItemClassificationSystemCode	Code	The Classification System for the Additional Trade Item Classification.	Use code 58.	additionalClassificationAgencyName

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
FDA Premarket Submission Number	TradeItem Classification	Attribute	additionalTradeItemClassificationCode	AdditionalTradeItemClassificationCode	Category code based on alternate classification schema chosen in addition to the Global Product Classification (GPC).	Populate with the FDA Premarket Submission Number. If there is a Supplement Number, place a colon (":") after the Premarket Submission Number then add the Submission Number. Repeat these attributes and process for all applicable FDA Premarket Submission Numbers and Supplement Numbers.	additionalClassificationCategoryCode
Supplement Number						If there is a Supplement Number, place a colon (":") after the Premarket Submission Number then add the Submission Number. Repeat these attributes and process for all applicable FDA Premarket Submission Numbers and Supplement Numbers.	See FDA Premarket Submission Number
FDA Product Code							

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Product Code	GDSNTradeItemClassification	Attribute	additionalTradeItemClassificationSystemCode	Code	The Classification System for the Additional Trade Item Classification.	Use code 43	additionalClassificationAgencyName
Product Code	TradeItemClassification	Attribute	additionalTradeItemClassificationCode	AdditionalTradeItemClassificationCode	Category code based on alternate classification schema chosen in addition to the Global Product Classification (GPC).	Code value managed by FDA.	additionalClassificationCategoryCode
Product Code Name						FDA will populate based on the FDA Product Code	
FDA Listing							
FDA Listing Number	AVP		fDAMedicalDeviceListing	String	Most Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to list the devices that are made a	AVP-fDAMedicalDeviceListing	fDAMedicalDeviceListing (AVP)
(Future change)	AdditionalKeyDataTypes	Attribute	additionalTradeItemIdentificationTypeCode	Code	This code will be used to cross-reference the Vendors internal trade item number to the GTIN in a one to one relationship.	Code to be determined when deployed in 2016.	additionalTradeItemIdentificationType
(Future change)	GS1IdentificationComponents	Attribute	additionalTradeItemIdentification	AdditionalTradeItemIdentification	Alternative means to the Global Trade Item Number to identify a trade item.		additionalTradeItemIdentificationValue
GMDN							

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Code (SPL-GMDN Preferred Term Code)	GDSNTradeItemClassification	Attribute	additionalTradeItemClassificationSystemCode	Code	The Classification System for the Additional Trade Item Classification.	Use code 35	additionalClassificationAgencyName
Code (SPL-GMDN Preferred Term Code)	TradeItemClassification	Attribute	additionalTradeItemClassificationCode	AdditionalTradeItemClassificationCode	Category code based on alternate classification schema chosen in addition to the Global Product Classification (GPC).	Code value managed by GMDN/FDA. Only either the GMDN or FDA Code is provided to the GUDID, the FDA will derive the actual term from a mapping to the GMDN or FDA Preferred term listing.	additionalClassificationCategoryCode
SPL Name-FDA Preferred Term Code	GDSNTradeItemClassification	Attribute	additionalTradeItemClassificationSystemCode	Code	The Classification System for the Additional Trade Item Classification.	Use code 63	additionalClassificationAgencyName
SPL Name-FDA Preferred Term Code	TradeItemClassification	Attribute	additionalTradeItemClassificationCode	AdditionalTradeItemClassificationCode	Category code based on alternate classification schema chosen in addition to the Global Product Classification (GPC).	Code value managed by GMDN/FDA. Only either the GMDN or FDA Code is provided to the GUDID, the FDA will derive the actual term from a mapping to the GMDN or FDA Preferred term listing.	additionalClassificationCategoryCode

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Name	GDSNTradeItemClassification	Attribute	additionalTradeItemClassificationCodeDescription	string (Text 1-200 Characters)	Description of the additional classification bundle (code/agency + description).	FDA will populate based on the GMDN Code. Can be provided via GDSN for supply chain purposes, but will not be populated to the GUDID from GDSN.	additionalClassificationCategoryDescription
Definition						FDA will populate based on the GMDN Code provided.	
Device Characteristics							
For Single-Use	MedicalDeviceTradeItemModule	Attribute	manufacturerDeclaredReusabilityTypeCode	Code	Determines if the product is intended for single or multiple uses, including the number of validated cycles and the number of times a product can be used according to the manufacturer specifications. It is suggested that medical providers consult the device manufacturer's Instruction For Use (IFU) for full reusability instructions.	LOGICAL POPULATION- (Logical BOOLEAN value of TRUE from the population of a value of SINGLE_USE or REUSABLE_SAME_PATIENT in manufacturerDeclaredReusabilityType, all other values equate to a FALSE value)	manufacturerDeclaredReusabilityType
Production Identifier(s) on Label							

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Lot or Batch Number	Packaging MarkingModule	Attribute	hasBatchNumber	Boolean	Indication whether the base trade item is batch or lot number requested by law, not batch or lot number requested by law but batch or lot number allocated, or not batch or lot number allocated. A batch or lot number is a manufacturer assigned code used to identify a trade item's trade item on batch or lot. Differs from Serial Number which is a manufacturer assigned code during the trade item on cycle to identify a unique trade item.		hasBatchNumber
Manufacturing Date	Packaging MarkingModule	Attribute	tradeItemDateOnPackagingTypeCode	Code	Indicates the type of date marked on the packaging for example Best Before Date.	Use code value-PRODUCTION_DATE	isPackageMarkedWithManufactureDate
Serial Number	Packaging MarkingModule	Attribute	serialNumberLocationCode	Code	The location on the item or packaging of a serial number. A serial number is a code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime for example a Microscope model AC-2 with serial number 1234568 and microscope mo	LOGICAL POPULATION-(Logical BOOLEAN value of TRUE from the population of any value except NOT_MARKED in serialNumberLocationCode)	serialNumberLocationCode

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Expiration Date	Packaging MarkingModule	Attribute	tradeItemDateOnPackagingTypeCode	Code	Indicates the type of date marked on the packaging for example Best Before Date.	LOGICAL POPULATION-(Logical BOOLEAN value of TRUE from the population of either values of EXPIRATION_DATE or BEST_BEFORE_DATE in tradeItemDateOnPackagingTypeCode other values or when no value is provided would equate to a value of FALSE)	packagingMarkedExpirationDateType
Donation Identification Number	AVP		donationIdentificationNumberMarked	Boolean	Indicates the device is managed by a Donation Identification Number. This number can be found on the device label or packaging. The Donation Identification Number is applicable to devices that are also regulated as HCT/Ps and is a number that is assigned	AVP-donationIdentificationNumberMarked	donationIdentificationNumberMarked
Latex Information							

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).	HealthcareItemInformationModule	Attribute	doesTradeItemContainLatex	NonBinaryLogicEnumeration	An indication that the trade item has a positive latex reference on the Trade Item's labeling.	This definition is currently listed on the Global Data Dictionary, but will be changed in a future GDSN release to the definition and wording at this link. Please use this new wording when populating the attribute.	doesTradeItemContainLatex
Device labeled as "Not made with natural rubber latex"	HealthWellnessPackagingMarkingModule	Attribute	packagingMarkedFreeFromCode	Code	Indication of the food ingredients that the package is marked free from.	Use value of FREE_FROM_LATEX	packageMarksFreeFrom
Prescription Status							
Prescription Use (Rx)	SalesInformationModule	Attribute	consumerSalesConditionCode	Code	A code depicting restrictions imposed on the Trade Item regarding how it can be sold to the consumer for example Prescription Required.	Use value of PRESCRIPTION_REQUIRED	ConsumerSalesCondition
Over the Counter (OTC)	SalesInformationModule	Attribute	consumerSalesConditionCode	Code	A code depicting restrictions imposed on the Trade Item regarding how it can be sold to the consumer for example Prescription Required.	Use value of OTC	ConsumerSalesCondition
MRI Safety Status							
What MRI safety information does the labeling contain?	MedicalDeviceTradeItemModule	Attribute	mRICompatibilityCode	Code	This is an identification of the compatibility of a trade item for use in the presence of a Magnetic Resonance Imaging (MRI) system.		mRICompatibility

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Clinically Relevant Size							
Size Type	AVP		clinicalSizeType	Code		AVP-clinicalSizeType	clinicalSizeType
Size Value	AVP		clinicalSizeValue	Measurement		AVP-clinicalSizeValue and clinicalSizeValueUoM	clinicalSizeValue + UoM
Size Unit of Measure	AVP		clinicalSizeValue	Measurement		AVP-clinicalSizeValue and clinicalSizeValueUoM	clinicalSizeValue + UoM
Size Type Text (SPL Name: "Size Text")	AVP		clinicalSizeText	String	When the clinicalSizeType is coded as "DEVICE_SIZE_TEXT_SPECIFY", this is the text used to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user.	AVP-clinicalSizeText	clinicalSizeText
Storage and Handling							
Storage and Handling Type	TradeItemTemperatureInformationModule	Attribute	temperatureQualifierCode	Code	Code qualifying the type of a temperature requirement for example Storage.		storageHandlingTemperatureMaximum, storageHandlingTemperatureMinimum, transportationMaximumTemperature, transportationMinimumTemperature

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
High Value (SPL Name: "Storage and Handling High Value")	TradeItemTemperatureInformationModule	Attribute	maximumTemperature	TemperatureMeasurement	The maximum temperature that a trade item can be held below defined by the manufacturer without affecting product safety or quality.		storageHandlingTemperatureMaximum, transportationMaximumTemperature
Low Value (SPL Name: "Storage and Handling Low Value")	TradeItemTemperatureInformationModule	Attribute	minimumTemperature	TemperatureMeasurement	The minimum temperature that a trade item can be held below defined by the manufacturer without affecting product safety or quality.		storageHandlingTemperatureMinimum, transportationMinimumTemperature
Unit of Measure (SPL Name: "Storage and Handling Unit of Measure")	MeasurementandQuantityDataTypes	Attribute	temperatureMeasurementUnitCode	Code	Any standardized, reproducible unit that can be used to measure any physical property.		storageHandlingTemperatureMaximum, storageHandlingTemperatureMinimum, transportationMaximumTemperature, transportationMinimumTemperature
Storage and Handling Type	AVP		storageEnvironmentAtmosphericPressureMaximum	Measurement	The maximum pressure at which the trade item can be stored and handled. This uses a measurement consisting of a unit of measure and a value	AVP-storageEnvironmentAtmosphericPressureMaximum	storageEnvironmentAtmosphericPressureMaximum, storageEnvironmentAtmosphericPressureMinimum
Storage and Handling Type	AVP		storageEnvironmentAtmosphericPressureMinimum	Measurement	The minimum pressure at which the trade item can be stored and handled. This uses a measurement consisting of a unit of measure and a value	AVP-storageEnvironmentAtmosphericPressureMinimum	storageEnvironmentAtmosphericPressureMaximum, storageEnvironmentAtmosphericPressureMinimum

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
High Value (SPL Name: "Storage and Handling High Value")	AVP		storageEnvironmentAtmosphericPressureMaximum	Measurement	The maximum pressure at which the trade item can be stored and handled. This uses a measurement consisting of a unit of measure and a value	AVP-storageEnvironmentAtmosphericPressureMaximum	storageEnvironmentAtmosphericPressureMaximum
Unit of Measure (SPL Name: "Storage and Handling Unit of Measure")	AVP		storageEnvironmentAtmosphericPressureMaximum	Measurement	The maximum pressure at which the trade item can be stored and handled. This uses a measurement consisting of a unit of measure and a value	AVP-storageEnvironmentAtmosphericPressureMaximum	storageEnvironmentAtmosphericPressureMaximum
Low Value (SPL Name: "Storage and Handling Low Value")	AVP		storageEnvironmentAtmosphericPressureMinimum	Measurement	The minimum pressure at which the trade item can be stored and handled. This uses a measurement consisting of a unit of measure and a value	AVP-storageEnvironmentAtmosphericPressureMinimum	storageEnvironmentAtmosphericPressureMinimum
Unit of Measure (SPL Name: "Storage and Handling Unit of Measure")	AVP		storageEnvironmentAtmosphericPressureMinimum	Measurement	The minimum pressure at which the trade item can be stored and handled. This uses a measurement consisting of a unit of measure and a value	AVP-storageEnvironmentAtmosphericPressureMinimum	storageEnvironmentAtmosphericPressureMinimum
Storage and Handling Type	TradeItemHumidityInformationModule	Attribute	humidityQualifierCode	Code	Code qualifying the type of a temperature for example STORAGE.		storageHandlingHumidityMaximum, storageHandlingHumidityMinimum
High Value (SPL Name: "Storage and Handling High Value")	TradeItemHumidityInformationModule	Attribute	maximumHumidityPercentage	Decimal	The maximum humidity in percentages that the goods should be stored in.		storageHandlingHumidityMaximum

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Low Value (SPL Name: "Storage and Handling Low Value")	TradeItem HumidityInformationModule	Attribute	minimumHumidityPercentage	Decimal	The maximum humidity in percentages that the goods should be stored in.		storageHandlingHumidityMinimum
Unit of Measure (SPL Name: "Storage and Handling Unit of Measure")						LOGICAL POPULATION- (Logical of PERCENT from the population of any value in storageHandlingHumidityMaximum and/or storageHandlingHumidityMinimum)	Data Pool to default on outbound message
Storage and Handling Type	AVP		transportationEnvironmentAtmosphericPressMax	Float	The maximum atmospheric pressure in which the item should be transported to remain usable. This value is the value above which the trade item should not be subjected.	AVP-transportationEnvironmentAtmosphericPressureMaximum	transportationEnvironmentAtmosphericPressureMaximum, transportationEnvironmentAtmosphericPressureMinimum
Storage and Handling Type	AVP		transportationEnvironmentAtmosphericPressMin	Float	The minimum atmospheric pressure in which the item should be transported to remain usable. This value is the value below which the trade item should not be subjected.	AVP-transportationEnvironmentAtmosphericPressureMinimum	transportationEnvironmentAtmosphericPressureMaximum, transportationEnvironmentAtmosphericPressureMinimum
High Value (SPL Name: "Storage and Handling High Value")	AVP		transportationEnvironmentAtmosphericPressMaxUoM	String	Unit of measure for the attribute transportationEnvironmentAtmosphericPressMax	AVP-transportationEnvironmentAtmosphericPressureMaximum	transportationEnvironmentAtmosphericPressureMaximum

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Unit of Measure (SPL Name: "Storage and Handling Unit of Measure")	AVP		transportationEnvironmentAtmosphericPressMaxUoM	String	Unit of measure for the attribute transportationEnvironmentAtmosphericPressMax	AVP-transportationEnvironmentAtmosphericPressureMaximum	transportationEnvironmentAtmosphericPressureMaximum
Low Value (SPL Name: "Storage and Handling Low Value")	AVP		transportationEnvironmentAtmosphericPressMin	Float	The minimum atmospheric pressure in which the item should be transported to remain usable. This value is the value below which the trade item should not be subjected.	AVP-transportationEnvironmentAtmosphericPressureMinimum	transportationEnvironmentAtmosphericPressureMinimum
Unit of Measure (SPL Name: "Storage and Handling Unit of Measure")	AVP		transportationEnvironmentAtmosphericPressMin	Float	The minimum atmospheric pressure in which the item should be transported to remain usable. This value is the value below which the trade item should not be subjected.	AVP-transportationEnvironmentAtmosphericPressureMinimum	transportationEnvironmentAtmosphericPressureMinimum
Storage and Handling Type	TradeItemHumidityInformationModule	Attribute	humidityQualifierCode	Code	Code qualifying the type of a temperature for example STORAGE.		transportationHumidityMaximum, transportationHumidityMinimum
High Value (SPL Name: "Storage and Handling High Value")	TradeItemHumidityInformationModule	Attribute	maximumHumidityPercentage	Decimal	The maximum humidity in percentages that the goods should be stored in.		transportationHumidityMaximum
Low Value (SPL Name: "Storage and Handling Low Value")	TradeItemHumidityInformationModule	Attribute	minimumHumidityPercentage	Decimal	The maximum humidity in percentages that the goods should be stored in.		transportationHumidityMinimum

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Unit of Measure (SPL Name: "Storage and Handling Unit of Measure")						LOGICAL POPULATION- (Logical of PERCENT from the population of any value in transportationHumidityMaximum and/or transportationHumidityMinimum)	Data Pool to default on outbound message
Special Storage Conditions	Consumer InstructionsModule	Attribute	consumerStorageInstructions	Description1000 (Free Text 1-1000 Characters) (Language Qualified)	Expresses in text the consumer storage instructions of a product which are normally held on the label or accompanying the product. This information may or may not be labeled on the pack. Instructions may refer to a suggested storage temperature, a specific storage requirement. Allows for the representation of the same value in different languages.		consumerUsageStorageInstructions
Sterilization Method							

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Device Packaged as Sterile	MedicalDeviceTradeItemModule	Attribute	initialManufacturerSterilisationCode	Code	Type(s) of sterilisation that may have been performed by the manufacturer if a trade item is sterile when it comes from the manufacturer. Sterilisation refers to any process that effectively kills or eliminates transmissible agents (such as fungi, bacteria, viruses, prions and spore forms etc.) from a surface, equipment, foods, medications, or biological culture medium. Some methods of sterilisation are through the application of heat, radiation, and ethylene. Type(s) of sterilisation that may have been performed by the manufacturer if a trade item is sterile when it comes from the manufacturer. Sterilisation refers to any process that effectively kills or eliminates transmissible agents (such as fungi, bacteria, viruses, prions and spore forms etc.) from a surface, equipment, foods, medications, or biological culture medium. Some methods of sterilisation are through the application of heat, radiation, and ethylene.	LOGICAL POPULATION- (Logical BOOLEAN value of TRUE from the population of any value in initialManufacturer Sterilisation)	initialManufacturerSterilisation

© 2015 GS1 AISBL

FDA GUDID Data Element	Module	Content	Attribute/ Role	Datatype/ Secondary Class	Definition	GDSN Notes	GDSN v2.8 Attribute Name
Requires Sterilization Prior to Use			-			LOGICAL POPULATION- (Logical BOOLEAN value of TRUE from the population of any value in initialSterilisationPriorToUse)	Data Pool to default on outbound message
Sterilization Method	MedicalDeviceTradeItemModule	Attribute	initialSterilisationPriorToUseCode	Code	This is an indication of the type(s) of sterilisation that is required to be completed by a healthcare provider prior to initial use of the healthcare trade item. Sterilisation refers to any process that effectively kills or eliminates transmissible agent		initialSterilisationPriorToUse

© 2015 GS1 AISBL

5 FDA GUDID Mapping to GS1 Code Values

The list below are FDA GUDID code values mapped to GS1 GDSN Code values. For some of these attributes, there may be additional code values available for use in GDSN not listed. This list focuses on just the values applicable to the GUDID mapping. Where the terming “PENDING” is utilised, it means actual code values have either not been identified by the FDA, or that a code is in process with the Global Standards Management Process (GSMP), but not yet assigned.

Figure 5.1- GDSN to GUDID Attribute Table legend

Header	Definition
FDA GUDID Code- Attribute- Code Group	The name of the FDA GUDID Data Element for which the code being described is relevant.
Code Value	The name of the code value or entry list value as assigned in the FDA GUDID.
GS1 GDSN Attribute Name	The name of the attribute as listed in the GS1 Global Data Dictionary (GDD) for use with GDSN v3.1.
GS1 GDSN Code Value	The code value for the specified GS1 GDSN attribute.
GS1 GDSN Code Description (where applicable)	A descriptive term for the specified code value where the code value is not fully descriptive. This is only populated where it is appropriate or needed.
Definition	Text defining the code value.

© 2015 GS1 AISBL

Figure 5.2- GDSN to GUDID Code Mapping Table

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Labeler DUNS Number			additionalPartyIdentificationTypeCode	DUNS	DUNS	Data Universal Numbering System. It is a nine digit numbering system which uniquely identifies an individual business. The DUNS number is a nine-digit number issued by Dun & Bradstreet assigned to each business location in the D&B database having a unique, separate, and distinct operation for the purpose of identifying them. A DUNS number is also a way in which separate corporate entities, having no official relationship, can be branded as one by sharing one DUNS number among the affiliated companies.
Labeler DUNS Number			additionalPartyIdentificationTypeCode	DUNS_PLUS_FOUR	DUNS+4	The DUNS+4 refers to the DUNS number assigned by Dun and Bradstreet, plus a 4- character suffix that is assigned by the vendor to establish additional Central Contractor Registration (CCR) database records for identifying alternative electronic funds transfer (EFT) accounts for the same vendor located at the same physical address. Dun and Bradstreet has no affiliation with the 4-character suffix.
Code (SPL-GMDN Preferred Term Code)			additionalTradeItemClassificationCode	35	GMDN	Global Medical Devices Nomenclature (GMDN)

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
FDA Premarket Submission Number			additionalTradeItemClassificationCode	58	FDA Premarket Submission Number	FDA Premarket Submission Number is a number associated with the regulatory decision regarding the applicant's legal right to market a medical device for the following submission types: 510(k), PMA, PDP, HDE, BLA, and NDA.
Product Code			additionalTradeItemClassificationCode	43	US FDA PCCD	US FDA Product Code Classification Database: The Product Classification Database contains medical device names and associated information developed by the Center for Devices and Radiological Health (CDRH) in support of its mission. This database contains device names and their associated product codes. The name and product code identify the generic category of a device for FDA. The Product Code assigned to a device is based upon the medical device product classification designated under 21 CFR Parts 862-892.
SPL Name- FDA Preferred Term Code			additionalTradeItemClassificationCode	65	FDA Preferred Term Code	FDA Preferred Term Code, Unique four-character value assigned by the FDA to indicate a GMDN Preferred Term without exposing the GMDN PT Code.
FDA Medical Device Listing Number			additionalTradeItemClassificationCode			**CODE PENDING**

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Secondary DI Number	HIBCC		additionalTradeItemIdentification			Health Industry Business Communication Barcode: An alphanumeric identification number used as a common identifier within the healthcare industry across different locations. In the Netherlands, this code is managed by the European Health Industry Business Communications Council.
Secondary DI Number	ICCBBA					**CODE PENDING**
Version or Model			additionalTradeItemIdentification	MODEL_NUMBER	Model Number	An identification number which defines the configuration of the product in addition to the Item number. This is typically printed or otherwise attached to an item. In electronics, this number is typically found around or near a serial number.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Catalog Number			additionalTradeItemIdentificationTypeCode	SUPPLIER_ASSIGNED	Supplier Assigned	The additional Trade Item Identification value populated has been developed and assigned by the party which provides service(s) and/or manufactures or otherwise has possession of the goods and consigns or makes them available in trade. This number is a base model or style number assigned to the product and may be the same for several GTINs where they are variations of each other. For example a coffee mug with 3 GTINs one each for the brown mug, the white mug, and the black mug might all be the supplier assigned number of AB123. Use of this value is recommended in the absence of a Model Number or Manufacturer's Part Number.
Secondary DI Number	GS1		additionalTradeItemIdentificationTypeCode			**Not needed as there can only be one GTIN for an item and therefore can not be a secondary GTIN.**
Size Type	Angle		clinicalSizeType	ANGLE		Temporary GDSN value pending future GDSN deployment.
Size Type	Area/Surface Area		clinicalSizeType	AREA_SURFACE_AREA		Temporary GDSN value pending future GDSN deployment.
Size Type	Circumference		clinicalSizeType	CIRCUMFERENCE		Temporary GDSN value pending future GDSN deployment.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Size Type	Depth		clinicalSizeType	DEPTH		Temporary GDSN value pending future GDSN deployment.
Size Type	Device Size Text, specify		clinicalSizeType	DEVICE_SIZE_TEXT_SPECIFY		Temporary GDSN value pending future GDSN deployment.
Size Type	Catheter Gauge (Formerly French Catheter Gauge)		clinicalSizeType	CATHETER_GAUGE		Temporary GDSN value pending future GDSN deployment.
Size Type	Height		clinicalSizeType	HEIGHT		Temporary GDSN value pending future GDSN deployment.
Size Type	Length		clinicalSizeType	LENGTH		Temporary GDSN value pending future GDSN deployment.
Size Type	Lumen/Inner Diameter (formerly Lumen Diameter)		clinicalSizeType	LUMEN_INNER_DIAMETER		Temporary GDSN value pending future GDSN deployment.
Size Type	Needle Gauge		clinicalSizeType	NEEDLE_GAUGE		Temporary GDSN value pending future GDSN deployment.
Size Type	Outer Diameter		clinicalSizeType	OUTER_DIAMETER		Temporary GDSN value pending future GDSN deployment.
Size Type	Pore size		clinicalSizeType	PORE_SIZE		Temporary GDSN value pending future GDSN deployment.
Size Type	Pressure		clinicalSizeType	PRESSURE		Temporary GDSN value pending future GDSN deployment.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Size Type	Total Volume		clinicalSizeType	TOTAL_VOLUME		Temporary GDSN value pending future GDSN deployment.
Size Type	Width		clinicalSizeType	WIDTH		Temporary GDSN value pending future GDSN deployment.
Size Type	Weight		clinicalSizeType	WEIGHT		Temporary GDSN value pending future GDSN deployment.
Customer Contact Email			communicationChannelCode	EMAIL	eMail	Creating/sending/receiving of unstructured free text messages or documents using computer network, a mini-computer or an attached modem and regular telephone line or other electronic transmission media.
Customer Contact Phone			communicationChannelCode	TELEPHONE	Telephone	Voice/data transmission by telephone.
Over the Counter (OTC)			consumerSalesConditionCode	OTC		Over the Counter- products that may be sold without a prescription. These products are generally available without restrictions.
Prescription Use (Rx)			consumerSalesConditionCode	PRESCRIPTION_REQUIRED		Trade item may only be sold or dispensed under the direction of a prescription.
N/A			contactTypeCode	CXC	Consumer Support (GS1 Code)	The party which provides product support to the end user of a trade item or a service (GS1 Code)
Combination Product			groupedProduct	COMBINATION		

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Kit			groupedProduct	KIT		
(Kit and Combination Product)			groupedProduct	KIT_AND_COMBINATION		
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).			doesTradeItemContainLatex	FALSE		The Brand Owner labeling does not state the Trade Item contains latex or may state that the Trade Item is free from latex.
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).			doesTradeItemContainLatex	TRUE		Brand Owner labeling states the Trade Item contains latex.
Storage and Handling Type	Storage Environment Humidity		humidityQualifierCode	STORAGE_HANDLING		Trade Item is being stored or handled.
Storage and Handling Type	Handling Environment Humidity		humidityQualifierCode	TRANSPORTATION		Trade item is in process of being transported in the supply chain.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	CHLORINE_DIOXIDE		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	DRY_HEAT		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	ETO_ETHYLENE_OXIDE		A gas that is commonly used to sterilize objects sensitive to temperatures greater than 60 °C such as plastics, optics and electrics. Ethylene oxide treatment is generally carried out between 30 °C and 60 °C with relative humidity above 30% and a gas concentration between 200 and 800 mg/L for at least three hours. Ethylene oxide penetrates well, moving through paper, cloth, and some plastic films and is highly effective.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	HIGH_INTENSITY_LIGHT_OR_PULSE_LIGHT		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	HIGH-LEVEL_DISINFECTANT		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	HYDROGEN_PEROXIDE		Another chemical sterilizing agent. It is relatively non-toxic once diluted to low concentrations (although a dangerous oxidizer at high concentrations), and leaves no residue.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	ETHANOL		A chemical sterilisation method that utilises ethanol as the sterilisation method.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	FORMALDEHYDE		A chemical sterilisation agent used to provide sterilisation. Items being sterilized are usually immersed in the formaldehyde for a pre-determined time period.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	GLUTERALDEHYDE		A colourless liquid with a pungent odour used to sterilize medical and dental equipment. It is also used for industrial water treatment and as a chemical preservative. Glutaraldehyde is an oily liquid at room temperature (density 1.06 g/mL), and miscible with water, alcohol, and benzene.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	LIQUID_CHEMICAL		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	MICROWAVE_RADIATION		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	AUTOCLAVE		Autoclave (Steam) is a method of sterilisation that utilises pressure and heat to achieve a sterile environment.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	NITROGEN_DIOXIDE		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	OZONE		Is a method often times used in industrial settings to sterilize water and air, as well as a disinfectant for surfaces. It has the benefit of being able to oxidize most organic matter. It is a toxic and unstable gas that must be produced on-site, so it is not practical to use in many settings.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	PERACETIC_ACID		A chemical in the organic peroxide family. It is a bright, colorless liquid with a characteristic acrid acetic acid type odor. It has a strong oxidizing potential, is highly corrosive, and can explode at temperatures exceeding 110 °C.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	BETA_RADIATION		Beta particles are able to penetrate living matter to a certain extent (radiation intensity from a small source of radioactive material decreases as one over the distance squared) and can change the structure of struck molecules.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	GAMMA_RADIATION		Gamma rays are very penetrating and are commonly used for sterilisation of disposable medical equipment, such as syringes, needles, cannulas and IV sets. Gamma radiation requires bulky shielding for the safety of the operators; they also require storage of a radioisotope (usually Cobalt-60), which continuously emits gamma rays (it cannot be turned off, and therefore always presents a hazard in the area of the facility).
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	SOUND_WAVES		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	SUPERCRITICAL_CARBON_DIOXIDE		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	UV_LIGHT		Useful for sterilisation of surfaces and some transparent objects. Many objects that are transparent to visible light absorb UV. UV irradiation is routinely used to sterilize the interiors of biological safety cabinets between uses.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Device Packaged as Sterile	TRUE		initialManufacturerSterilisationCode	UNSPCEIFIED		Trade Item Manufacturer has not specified the sterilisation method(s) of the trade item.
Sterilization Method	Chlorine Dioxide		initialSterilisationPriorToUseCode	CHLORINE_DIOXIDE		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.
Sterilization Method	Dry Heat		initialSterilisationPriorToUseCode	DRY_HEAT		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.
Sterilization Method	Ethylene Oxide		initialSterilisationPriorToUseCode	ETO_ETHYLENE_OXIDE		A gas that is commonly used to sterilize objects sensitive to temperatures greater than 60 °C such as plastics, optics and electrics. Ethylene oxide treatment is generally carried out between 30 °C and 60 °C with relative humidity above 30% and a gas concentration between 200 and 800 mg/L for at least three hours. Ethylene oxide penetrates well, moving through paper, cloth, and some plastic films and is highly effective.
Sterilization Method	High Intensity Light or Pulse Light		initialSterilisationPriorToUseCode	HIGH_INTENSITY_LIGHT_OR_PULSE_LIGHT		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Sterilization Method	High-level Disinfectant		initialSterilisationPriorToUseCode	HIGH-LEVEL_DISINFECTANT		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.
Sterilization Method	Hydrogen Peroxide		initialSterilisationPriorToUseCode	HYDROGEN_PEROXIDE		Another chemical sterilizing agent. It is relatively non-toxic once diluted to low concentrations (although a dangerous oxidizer at high concentrations), and leaves no residue.
Sterilization Method	Liquid Chemical		initialSterilisationPriorToUseCode	ETHANOL		A chemical sterilisation method that utilises ethanol as the sterilisation method.
Sterilization Method	Liquid Chemical		initialSterilisationPriorToUseCode	FORMALDEHYDE		A chemical sterilisation agent used to provide sterilisation. Items being sterilized are usually immersed in the formaldehyde for a pre determined time period.
Sterilization Method	Liquid Chemical		initialSterilisationPriorToUseCode	GLUTERALDEHYDE		A colourless liquid with a pungent odour used to sterilize medical and dental equipment. It is also used for industrial water treatment and as a chemical preservative. Glutaraldehyde is an oily liquid at room temperature (density 1.06 g/mL), and miscible with water, alcohol, and benzene.
Sterilization Method	Liquid Chemical		initialSterilisationPriorToUseCode	LIQUID_CHEMICAL		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Sterilization Method	Microwave Radiation		initialSterilisationPriorToUseCode	MICROWAVE_RADIATION		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.
Sterilization Method	Moist Heat or Steam		initialSterilisationPriorToUseCode	AUTOCLAVE		Autoclave (Steam) is a method of sterilisation that utilises pressure and heat to achieve a sterile environment.
Sterilization Method	Nitrogen Dioxide		initialSterilisationPriorToUseCode	NITROGEN_DIOXIDE		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.
Sterilization Method	Ozone		initialSterilisationPriorToUseCode	OZONE		Is a method often times used in industrial settings to sterilize water and air, as well as a disinfectant for surfaces. It has the benefit of being able to oxidize most organic matter. It is a toxic and unstable gas that must be produced on-site, so it is not practical to use in many settings.
Sterilization Method	Peracetic Acid		initialSterilisationPriorToUseCode	PERACETIC_ACID		A chemical in the organic peroxide family. It is a bright, colorless liquid with a characteristic acrid acetic acid type odor. It has a strong oxidizing potential, is highly corrosive, and can explode at temperatures exceeding 110 °C.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Sterilization Method	Radiation		initialSterilisationPriorToUseCode	BETA_RADIATION		Beta particles are able to penetrate living matter to a certain extent (radiation intensity from a small source of radioactive material decreases as one over the distance squared) and can change the structure of struck molecules.
Sterilization Method	Radiation		initialSterilisationPriorToUseCode	GAMMA_RADIATION		Gamma rays are very penetrating and are commonly used for sterilisation of disposable medical equipment, such as syringes, needles, cannulas and IV sets. Gamma radiation requires bulky shielding for the safety of the operators; they also require storage of a radioisotope (usually Cobalt-60), which continuously emits gamma rays (it cannot be turned off, and therefore always presents a hazard in the area of the facility).
Sterilization Method	Sound Waves		initialSterilisationPriorToUseCode	SOUND_WAVES		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.
Sterilization Method	Supercritical Carbon Dioxide		initialSterilisationPriorToUseCode	SUPERCRITICAL_CARBON_DIOXIDE		This is a code value for population with the AVP attribute extendedInitialSterilisationPriorToUse. This value will be added to the SterilisationTypeCode list in a future GDSN release.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Sterilization Method	Ultraviolet Light		initialSterilisationPriorToUseCode	UV_LIGHT		Useful for sterilisation of surfaces and some transparent objects. Many objects that are transparent to visible light absorb UV. UV irradiation is routinely used to sterilize the interiors of biological safety cabinets between uses.
For Single-Use	FALSE		manufacturerDeclaredReusabilityTypeCode	LIMITED_REUSABLE		Manufacturer has indicated that product may be reused but has provided special instructions, limitations or guidelines around the reuse of this trade item.
For Single-Use	FALSE		manufacturerDeclaredReusabilityTypeCode	REUSABLE		Product can be reused
For Single-Use	TRUE		manufacturerDeclaredReusabilityTypeCode	REUSABLE_SAME_PATIENT		Product can only be reused for the same patient.
For Single-Use	TRUE		manufacturerDeclaredReusabilityTypeCode	SINGLE_USE		Item is not intended to be reused.
What MRI safety information does the labeling contain?	MR Safe		mRICompatibilityCode	MRI_SAFE		Indicates that the healthcare trade item is safe to use within a Magnetic Resonance Imaging (MRI) system.
What MRI safety information does the labeling contain?	MR Unsafe		mRICompatibilityCode	MRI_UNSAFE		Indicates that a healthcare trade item is not safe to use in an MRI system.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
What MRI safety information does the labeling contain?	MR Conditional		mRICompatibilityCode	MRI_COMPATIBLE		Indicates that a healthcare trade item is safe to use in the presence of a Magnetic Resonance Imaging (MRI) System
What MRI safety information does the labeling contain?	Labeling does not contain MRI Safety Information		mRICompatibilityCode	UNSPECIFIED		The manufacturer of the Trade Item has not communicated information on the compatibility of this trade item with a Magnetic Resonance Imaging (MRI) System.
Device labeled as "Not made with natural rubber latex"	TRUE		packagingMarkedFreeFromCode	FREE_FROM_LATEX		The item is physically marked being free from Latex (rubber) as approved by the appropriate authority of the target market.
Package Type	Intermediate bulk container, rigid plastic		packagingTypeCode	AA	Intermediate bulk container, rigid plastic	A Rigid Intermediate Bulk Container (RIBC) that is attached to a pallet or has the pallet integrated into the RIBC. The container is used for the transport and storage of fluids and other bulk materials. The
Package Type	Aerosol		packagingTypeCode	AE	Aerosol	A gas-tight, pressure-resistant container with a valve and propellant. When the valve is opened, propellant forces the product from the container in a fine or coarse spray pattern or stream. (e.g., a spray can dispensing paint, furniture polish, etc, under pressure). It does not include atomizers, because atomizers do not rely on a pressurised container to propel product from the container.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Package Type	Ampoule		packagingTypeCode	AM	Ampoule	A relatively small container made from glass or plastic tubing, the end of which is drawn into a stem and closed by fusion after filling. The bottom may be flat, convex, or drawn out. An ampule is opened by breaking the stem.
Package Type	Barrel		packagingTypeCode	BA	Barrel	A cylindrical packaging whose bottom end is permanently fixed to the body and top end (head) is either removable or non-removable.
Package Type	Bag in Box		packagingTypeCode	BBG	Bag in Box	Bag-In-Box or BIB is a type of container for the storage and transportation of liquids. It consists of a strong bladder, usually made of aluminium PET film or other plastics seated inside a corrugated fibreboard box. The box and internal bag can be fused together. In most cases there is nozzle or valve fixed to the bag. The nozzle can be connected easily to a dispensing installation or the valve allows for convenient dispensing.
Package Type	Bag		packagingTypeCode	BG	Bag	A preformed, flexible container, generally enclosed on all but one side, which forms an opening that may or may not be sealed after filling.
Package Type	Bucket		packagingTypeCode	BJ	Bucket	A container, usually cylindrical, can be equipped with a lid and a handle. (e.g., a pail made of metal, plastic, or other appropriate material).
Package Type	Basket		packagingTypeCode	BK	Basket	A semi rigid container usually open at the top traditionally used for gathering, shipping and marketing agricultural products.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Package Type	Bottle		packagingTypeCode	BO	Bottle	A container having a round neck of relatively smaller diameter than the body and an opening capable of holding a closure for retention of the contents. Specifically, a narrow-necked container as compared with a jar or wide-mouth container. The cross section of the bottle may be round, oval, square, oblong, or a combination of these. Bottles generally are made of glass or plastics, but can also be earthenware or metal. Bottle may be disposable, recyclable, returnable, or reusable.
Package Type	Blister pack		packagingTypeCode	BPG	Blister pack	A type of packaging in which the item is secured between a preformed (usually transparent plastic) dome or “bubble” and a paperboard surface or “carrier.” Attachment may be by stapling, heat-sealing, gluing, or other means. In other instances, the blister folds over the product in clam-shell fashion to form an enclosing container. Blisters are most usually thermoformed from polyvinyl chloride; however, almost any thermoplastic can be thermoformed into a blister.
Package Type	Brick		packagingTypeCode	BRI	Brick	A rectangular-shaped, stackable package designed primarily for liquids such as juice or milk

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Package Type	Box		packagingTypeCode	BX	Box	A non-specific term used to refer to a rigid, three-dimensional container with closed faces that completely enclose its contents and may be made out of any material. Even though some boxes might be reused or become resealed they could also be disposable depending on the product hierarchy.
Package Type	Cage		packagingTypeCode	CG	Cage	A container enclosed on at least one side by a grating of wires or bars that lets in air and light.
Package Type	Card		packagingTypeCode	CM	Card	A flat package to which the product is hung or attached for display.
Package Type	Clam Shell		packagingTypeCode	CMS	Clam Shell	A one-piece container consisting of two halves joined by a hinge area which allows the structure to come together to close. Clamshells get their name from their appearance to the shell of a clam, which it resembles both in form and function.
Package Type	Can		packagingTypeCode	CNG	Can	A metallic and generally cylindrical container of unspecified size which can be used for items of consumer and institutional sizes.
Package Type	Crate		packagingTypeCode	CR	Crate	A non-specific term usually referring to a rigid three-dimensional container with semi-closed faces that enclose its contents for shipment or storage. Crates could have an open or closed top and may have internal divers. Even though some crates might be reused or become resealed they could also be disposable depending on the product hierarchy.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Package Type	Case		packagingTypeCode	CS	Case	A non-specific term for a container designed to hold, house, and sheath or encase its content while protecting it during distribution, storage and/or exhibition. Cases are mostly intended to store and preserve its contents during the product's entire lifetime.
Package Type	Carton		packagingTypeCode	CT	Carton	A non-specific term for an open or re-closable container used mostly for perishable foods (e.g. eggs, or fruit).
Package Type	Cup\Tub		packagingTypeCode	CU	Cup\Tub	A flat-bottomed container that has a base of any shape and which may or not be closed with a lid. Usually made of paper, plastic or other materials these containers are typically used to contain mostly (but not exclusively) foods such as ice cream, margarine, yogurt, sour cream, confections, etc.
Package Type	Cylinder		packagingTypeCode	CY	Cylinder	A rigid cylindrical container with straight sides and circular ends of equal size.
Package Type	Envelope		packagingTypeCode	EN	Envelope	A predominantly flat container of flexible material having only two faces, and joined at three edges to form an enclosure. The non-joined edge provides a filling opening, which may later be closed by a gummed or adhesive flap, heat seal, tie string, metal clasp, or other methods.
Package Type	Gable Top		packagingTypeCode	GTG	Gable Top	A rectangular-shaped, non-stackable package designed primarily for liquids such as juice or milk

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Package Type	Jug		packagingTypeCode	JG	Jug	A container, normally cylindrical, with a handle and/or a lid or spout for holding and pouring liquids
Package Type	Jar		packagingTypeCode	JR	Jar	A rigid container made of glass, stone, earthenware, plastic or other appropriate material with a large opening, which is used to store products, (e.g., jams, cosmetics).
Package Type	Multipack		packagingTypeCode	MPG	Multipack	A bundle of products held together for ease of carriage by the consumer. A multipack is always a consumer unit.
Package Type	Not packed		packagingTypeCode	NE	Not packed	The item is provided without packaging.
Package Type	Net		packagingTypeCode	NT	Net	A container of meshwork material made from threads or strips twisted or woven to form a regular pattern with spaces between the threads that is used for holding, carrying, trapping, or confining something.
Package Type	Pallet Box		packagingTypeCode	PB	Pallet Box	A three-dimensional container which either has a pallet platform permanently attached at its base or alternatively requires a platform for its handling and storage as due to its constitution it cannot be handled without it. The characteristics of the platform should be specified using the pallet type code list
Package Type	Peel Pack		packagingTypeCode	PLP	Peel Pack	A package used for sterile products which may be torn open without touching the product inside.
Package Type	Pouch		packagingTypeCode	PO	Pouch	A preformed, flexible container, generally enclosed with a gusset seal at the bottom of the pack can be shaped/arranged to allow the pack to stand on shelf.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Package Type	Pot		packagingTypeCode	PT	Pot	A flat-bottomed container that has a base of any shape and which may or not be closed with a lid. Pots are usually made of cardboard, plastic, ceramic, metal or other materials and may be used for a wide array of products such as cosmetics, food/liquids, dairy products, plants.
Package Type	Tray		packagingTypeCode	PU	Tray	A shallow container, which may or may not have a cover, used for displaying, carrying items or carry for warehousing. Examples for TIIG • Plate • Cardboard carrier • Cellplate • Divider Sheet/Slip Sheet • Plastic-Wrapped Tray • Tray for bottles • Tray one layer no cover • Tray tablet • Tray Shrinkpacked • Tray/Tray pack • Other Information • This code also covers all 'ready to cook' plates in which some products are sold. • Divider Sheets/Slip Sheets which are used to hold layers on a pallet for efficient cross docking warehousing processes.
Package Type	Packed, unspecified		packagingTypeCode	PUG	Packed, unspecified	Packaging of the product (or products) is currently not on the list. Use this code when no suitable options are available and only while a Change Request is approved for the proper packaging type.
Package Type	Pallet		packagingTypeCode	PX	Pallet	A platform used to hold or transport unit loads.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Package Type	Rack		packagingTypeCode	RK	Rack	A non specific term identifying a framework or stand for carrying, holding, or storing items. Commonly on wheels and primarily used in the logistical functions to deliver items such as hanging garments, or items on shelves such as dairy products and bakery items and flowers.
Package Type	Reel		packagingTypeCode	RL	Reel	A spool on which thread, wire, film, etc, is wound. Any device on which a material may be wound. Usually has flanged ends and is used for shipping or processing purposes.
Package Type	Stretchwrapped		packagingTypeCode	STR	Stretchwrapped	In packaging, a high-tensile plastic film, stretched and wrapped repeatedly around an item or group of items to secure and maintain unit integrity. The use of stretch film to tightly wrap a package or a unit load in order to bind, protect and immobilize it for further handling or shipping.
Package Type	Shrinkwrapped		packagingTypeCode	SW	Shrinkwrapped	In packaging, a plastic film around an item or group of items which is heated causing the film to shrink, securing the unit integrity. The use of shrunken film to tightly wrap a package or a unit load in order to bind, protect and immobilize it for further handling or shipping.
Package Type	Sleeve		packagingTypeCode	SY	Sleeve	A non-rigid container usually made of paper, cardboard or plastic, that is open-ended and is slid over the contents for protection or presentation.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Package Type	Tube		packagingTypeCode	TU	Tube	A cylindrical container sealed on one end that could be closed with a cap or dispenser on the other end.
Package Type	Wrapper		packagingTypeCode	WRP	Wrapper	The process of enclosing all or part of an item with layers of flexible wrapping material (e.g., for an individually packed ice cream). Does not include items which are shrink-wrapped or vacuum-packed.
Package Type	Banded package		packagingTypeCode	X11	Banded package	Something used to bind, tie, or encircle the item or its packaging to secure and maintain unit integrity.
Package Type	Flexible Intermediate Bulk Container		packagingTypeCode	ZU	Flexible Intermediate Bulk Container	A non-rigid container used for transport and storage of fluids and other bulk materials. The construction of the IBC container and the materials used are chosen depending on the application.
Serial Number	TRUE		serialNumberLocationCode	MARKED_ON_TRADE_ITEM		Serial number is on the trade item.
Serial Number	FALSE		serialNumberLocationCode	NOT_MARKED		The trade item or its packaging is not marked
Serial Number	TRUE		serialNumberLocationCode	MARKED_ON_PACKAGING		Serial number is on the trade item's packaging.
Serial Number	TRUE		serialNumberLocationCode	MARKED_ON_PACKAGING_INSERT		Serial number is on the trade item's packaging insert.
Serial Number	TRUE		serialNumberLocationCode	UNKNOWN		Unknown location of marking.
Storage and Handling Type	Storage Environment Temperature		temperatureQualifierCode	STORAGE_HANDLING		Trade Item is being stored or handled.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Storage and Handling Type	Handling Environment Temperature		temperatureQualifierCode	TRANSPORTATION		Trade item is in process of being transported in the supply chain.
Manufacturing Date	TRUE (Manufacturing Date)		tradeItemDateOnPackagingTypeCode	PRODUCTION_DATE		The production date is the production or assembly date determined by the manufacturer. The date may refer to the trade item itself or to items contained.
Expiration Date	TRUE (Expiration Date)		tradeItemDateOnPackagingTypeCode	EXPIRATION_DATE		The expiration date is the date that determines the limit of consumption or use of a product. Its meaning is determined based on the trade item context (e.g., for food, the date will indicate the possibility of a direct health risk resulting from use of the product after the date, for pharmaceutical products, it will indicate the possibility of an indirect health risk resulting from the ineffectiveness of the product after the date). It is often referred to as “use by date” or “maximum durability date.”
Expiration Date	TRUE (Expiration Date)		tradeItemDateOnPackagingTypeCode	BEST_BEFORE_DATE		The best before date indicates the ideal consumption or best effective use date of a product. It is a statement about quality. It is often referred to as a sell by date or a minimum durability date.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Value	GS1 GDSN Code Description (where applicable)	Definition
Unit of Measure (SPL Name: "Storage and Handling Unit of Measure")	Celsius		temperatureMeasurementUnitCode	CEL		Celsius: (also historically known as centigrade) is a temperature scale, the freezing point of water is 0 degrees Celsius (°C) and the boiling point 100 °C (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 100 degrees apart.
Unit of Measure (SPL Name: "Storage and Handling Unit of Measure")	Fahrenheit		temperatureMeasurementUnitCode	FAH		The Fahrenheit temperature scale: the freezing point of water is 32 degrees Fahrenheit (°F) and the boiling point 212 °F (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 180 degrees apart.

Figure 5.2- The following are the Unit of Measures (UoM) which are used by FDA and the corresponding UoM used in GDSN

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Angle Units of Measure - {Angle}	deg {Degree}		netContent	Count	DD	Degree (Unit of Angle)	A measurement of plane angle, representing 1?360 of a full rotation; one degree is equivalent to ?/180 radians.
UoM- Area Units of Measure- {Area/Surface Area}	[sft_i} {Square foot}		netContent	Area	FTK	Square foot	A square foot is an area of a square whose sides are exactly 1 foot in length.
UoM- Area Units of Measure- {Area/Surface Area}	[sin_i} {Square inch}		netContent	Area	INK	Square inch	A square inch is an area of a square whose sides are exactly 1 inch in length.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Area Units of Measure- {Area/Surface Area}	cm2 {Square centimeter}		netContent	Area	CMK	Square centimetre	A square centimetre is an area of a square whose sides are exactly 1 centimetre in length.
UoM- Area Units of Measure- {Area/Surface Area}	m2 {Square meter}		netContent	Area	MTK	Square metre	A square metre is an area of a square whose sides are exactly 1 metre in length.
UoM- Area Units of Measure- {Area/Surface Area}	mm2 {Square millimeter}		netContent	Area	MMK	Square millimetre	A square millimetre is an area of a square whose sides are exactly 1 millimetre in length.
UoM- Gauge - French Units of Measure - {Catheter Gauge}	[Ch} {French }		clinicalSizeValue; height; width; depth; and netContent	Dimension	H79	French gauge	The French scale (most correctly abbreviated as Fr, but also often abbreviated as FR or F) is commonly used to measure the catheter size (Circumference is in millimeters), in which 1 Fr = 0.33 mm in diameter. In the French Gauge system as it is also known, the diameter in millimeters of the catheter can be determined by dividing the French size by 3, thus an increasing French size corresponds with a larger diameter catheter. The following equations summarize the relationships: D(mm) = Fr/3 or Fr = D(mm)*3
UoM- Gauge - Needle Units of Measure - {Needle Gauge	G {Gauge}		clinicalSizeValue; height; width; depth; and netContent	Dimension	AWG	Gauge	A number referring to the outer diameter of hypodermic or suture needles. Smaller gauge numbers indicate larger outer diameters. Inner diameter depends on both gauge and wall thickness. An increasing needle-gauge size corresponds to a smaller diameter needle. This is contrary to French Gauge where an increasing gauge size corresponds to a larger external diameter.
UoM- Length Size Units of Measure - {Circumference }	[ft_i} {Feet}		clinicalSizeValue; height; width; depth; and netContent	Dimension	FOT	Foot	The international foot is defined to be equal to 0.3048 meters.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Length Size Units of Measure - {Circumference }	[in_i} {Inch}		clinicalSizeValue; height; width; depth; and netContent	Dimension	INH	Inches	An international inch is defined to be equal to 25.4 millimeters.
UoM- Length Size Units of Measure - {Circumference }	[yd_i} {Yard }		clinicalSizeValue; height; width; depth; and netContent	Dimension	YRD	Yard	A yard is It is equal to 3 feet or 36 inches or 0.9144 meter.
UoM- Length Size Units of Measure - {Circumference }	cm {Centimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	CMT	Centimetre	A centimetre is equal to one hundredth of a metre.
UoM- Length Size Units of Measure - {Circumference }	dm {Decimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	DMT	Decimetre	A decimetre is equal to one tenth of a metre.
UoM- Length Size Units of Measure - {Circumference }	fm {Femtometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	A71	Femtometre	Femtometre- a quadrillionth of a metre (10 to the negative 15th power)
UoM- Length Size Units of Measure - {Circumference }	km {Kilometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	KMT	Kilometre	A kilometre is one thousand (1000) metres
UoM- Length Size Units of Measure - {Circumference }	m {Meter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MTR	Metre	The metre is the basic unit of length in the International System of Units (SI).

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Length Size Units of Measure - {Circumference }	mm {Millimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MMT	Millimetre	A millimetre is one thousandth of a metre (0.001)
UoM- Length Size Units of Measure - {Circumference }	nm {Nanometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C45	Nanometre	Nanometre- a billionth of a metre (10 to the negative 9th power)
UoM- Length Size Units of Measure - {Circumference }	pm {Picometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C52	Picometre	Picometre- a trillionth of a metre (10 to the negative 12th power)
UoM- Length Size Units of Measure - {Circumference }	um {Micrometer}		clinicalSizeValue; height; width; depth; and netContent	Volume	4G	Microlitre	A microlitre is one millionth of a litre
UoM- Length Size Units of Measure - {Depth}	[ft_i] {Feet}		clinicalSizeValue; height; width; depth; and netContent	Dimension	FOT	Foot	The international foot is defined to be equal to 0.3048 meters.
UoM- Length Size Units of Measure - {Depth}	[in_i] {Inch}		clinicalSizeValue; height; width; depth; and netContent	Dimension	INH	Inches	An international inch is defined to be equal to 25.4 millimeters.
UoM- Length Size Units of Measure - {Depth}	[yd_i] {Yard }		clinicalSizeValue; height; width; depth; and netContent	Dimension	YRD	Yard	A yard is It is equal to 3 feet or 36 inches or 0.9144 meter.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Length Size Units of Measure - {Depth}	cm {Centimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	CMT	Centimetre	A centimetre is equal to one hundredth of a metre.
UoM- Length Size Units of Measure - {Depth}	dm {Decimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	DMT	Decimetre	A decimetre is equal to one tenth of a metre.
UoM- Length Size Units of Measure - {Depth}	fm {Femtometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	A71	Femtometre	Femtometre- a quadrillionth of a metre (10 to the negative 15th power)
UoM- Length Size Units of Measure - {Depth}	km {Kilometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	KMT	Kilometre	A kilometre is one thousand (1000) metres
UoM- Length Size Units of Measure - {Depth}	m {Meter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MTR	Metre	The metre is the basic unit of length in the International System of Units (SI).
UoM- Length Size Units of Measure - {Depth}	mm {Millimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MMT	Millimetre	A millimetre is one thousandth of a metre (0.001)
UoM- Length Size Units of Measure - {Depth}	nm {Nanometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C45	Nanometre	Nanometre- a billionth of a metre (10 to the negative 9th power)
UoM- Length Size Units of Measure - {Depth}	pm {Picometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C52	Picometre	Picometre- a trillionth of a metre (10 to the negative 12th power)

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Length Size Units of Measure - {Depth}	um {Micrometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	4H	Micrometre	A micrometre is one millionth of a metre, also termed Micron.
UoM- Length Size Units of Measure - {Height}	[ft_i} {Feet}		clinicalSizeValue; height; width; depth; and netContent	Dimension	FOT	Foot	The international foot is defined to be equal to 0.3048 meters.
UoM- Length Size Units of Measure - {Height}	[in_i} {Inch}		clinicalSizeValue; height; width; depth; and netContent	Dimension	INH	Inches	An international inch is defined to be equal to 25.4 millimeters.
UoM- Length Size Units of Measure - {Height}	[yd_i} {Yard }		clinicalSizeValue; height; width; depth; and netContent	Dimension	YRD	Yard	A yard is It is equal to 3 feet or 36 inches or 0.9144 meter.
UoM- Length Size Units of Measure - {Height}	cm {Centimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	CMT	Centimetre	A centimetre is equal to one hundredth of a metre.
UoM- Length Size Units of Measure - {Height}	dm {Decimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	DMT	Decimetre	A decimetre is equal to one tenth of a metre.
UoM- Length Size Units of Measure - {Height}	fm {Femtometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	A71	Femtometre	Femtometre- a quadrillionth of a metre (10 to the negative 15th power)
UoM- Length Size Units of Measure - {Height}	km {Kilometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	KMT	Kilometre	A kilometre is one thousand (1000) metres

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Length Size Units of Measure - {Height}	m {Meter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MTR	Metre	The metre is the basic unit of length in the International System of Units (SI).
UoM- Length Size Units of Measure - {Height}	mm {Millimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MMT	Millimetre	A millimetre is one thousandth of a metre (0.001)
UoM- Length Size Units of Measure - {Height}	nm {Nanometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C45	Nanometre	Nanometre- a billionth of a metre (10 to the negative 9th power)
UoM- Length Size Units of Measure - {Height}	pm {Picometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C52	Picometre	Picometre- a trillionth of a metre (10 to the negative 12th power)
UoM- Length Size Units of Measure - {Height}	um {Micrometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	4H	Micrometre	A micrometre is one millionth of a metre, also termed Micron.
UoM- Length Size Units of Measure - {Length}	[ft_i] {Feet}		clinicalSizeValue; height; width; depth; and netContent	Dimension	FOT	Foot	The international foot is defined to be equal to 0.3048 meters.
UoM- Length Size Units of Measure - {Length}	[in_i] {Inch}		clinicalSizeValue; height; width; depth; and netContent	Dimension	INH	Inches	An international inch is defined to be equal to 25.4 millimeters.
UoM- Length Size Units of Measure - {Length}	[yd_i] {Yard }		clinicalSizeValue; height; width; depth; and netContent	Dimension	YRD	Yard	A yard is It is equal to 3 feet or 36 inches or 0.9144 meter.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Length Size Units of Measure - {Length}	cm {Centimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	CMT	Centimetre	A centimetre is equal to one hundredth of a metre.
UoM- Length Size Units of Measure - {Length}	dm {Decimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	DMT	Decimetre	A decimetre is equal to one tenth of a metre.
UoM- Length Size Units of Measure - {Length}	fm {Femtometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	A71	Femtometre	Femtometre- a quadrillionth of a metre (10 to the negative 15th power)
UoM- Length Size Units of Measure - {Length}	km {Kilometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	KMT	Kilometre	A kilometre is one thousand (1000) metres
UoM- Length Size Units of Measure - {Length}	m {Meter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MTR	Metre	The metre is the basic unit of length in the International System of Units (SI).
UoM- Length Size Units of Measure - {Length}	mm {Millimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MMT	Millimetre	A millimetre is one thousandth of a metre (0.001)
UoM- Length Size Units of Measure - {Length}	nm {Nanometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C45	Nanometre	Nanometre- a billionth of a metre (10 to the negative 9th power)
UoM- Length Size Units of Measure - {Length}	pm {Picometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C52	Picometre	Picometre- a trillionth of a metre (10 to the negative 12th power)

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Length Size Units of Measure - {Length}	um {Micrometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	4H	Micrometre	A micrometre is one millionth of a metre, also termed Micron.
UoM- Length Size Units of Measure - {Lumen/Inner Diameter}	[ft_i] {Feet}		clinicalSizeValue; height; width; depth; and netContent	Dimension	FOT	Foot	The international foot is defined to be equal to 0.3048 meters.
UoM- Length Size Units of Measure - {Lumen/Inner Diameter}	[in_i] {Inch}		clinicalSizeValue; height; width; depth; and netContent	Dimension	INH	Inches	An international inch is defined to be equal to 25.4 millimeters.
UoM- Length Size Units of Measure - {Lumen/Inner Diameter}	[yd_i] {Yard }		clinicalSizeValue; height; width; depth; and netContent	Dimension	YRD	Yard	A yard is It is equal to 3 feet or 36 inches or 0.9144 meter.
UoM- Length Size Units of Measure - {Lumen/Inner Diameter}	cm {Centimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	CMT	Centimetre	A centimetre is equal to one hundredth of a metre.
UoM- Length Size Units of Measure - {Lumen/Inner Diameter}	dm {Decimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	DMT	Decimetre	A decimetre is equal to one tenth of a metre.
UoM- Length Size Units of Measure - {Lumen/Inner Diameter}	fm {Femtometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	A71	Femtometre	Femtometre- a quadrillionth of a metre (10 to the negative 15th power)

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Length Size Units of Measure - {Lumen/Inner Diameter}	km {Kilometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	KMT	Kilometre	A kilometre is one thousand (1000) metres
UoM- Length Size Units of Measure - {Lumen/Inner Diameter}	m {Meter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MTR	Metre	The metre is the basic unit of length in the International System of Units (SI).
UoM- Length Size Units of Measure - {Lumen/Inner Diameter}	mm {Millimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MMT	Millimetre	A millimetre is one thousandth of a metre (0.001)
UoM- Length Size Units of Measure - {Lumen/Inner Diameter}	nm {Nanometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C45	Nanometre	Nanometre- a billionth of a metre (10 to the negative 9th power)
UoM- Length Size Units of Measure - {Lumen/Inner Diameter}	pm {Picometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C52	Picometre	Picometre- a trillionth of a metre (10 to the negative 12th power)
UoM- Length Size Units of Measure - {Lumen/Inner Diameter}	um {Micrometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	4H	Micrometre	A micrometre is one millionth of a metre, also termed Micron.
UoM- Length Size Units of Measure - {Outer Diameter}	[ft_i] {Feet}		clinicalSizeValue; height; width; depth; and netContent	Dimension	FOT	Foot	The international foot is defined to be equal to 0.3048 meters.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Length Size Units of Measure - {Outer Diameter}	[in_i] {Inch}		clinicalSizeValue; height; width; depth; and netContent	Dimension	INH	Inches	An international inch is defined to be equal to 25.4 millimeters.
UoM- Length Size Units of Measure - {Outer Diameter}	[yd_i] {Yard }		clinicalSizeValue; height; width; depth; and netContent	Dimension	YRD	Yard	A yard is It is equal to 3 feet or 36 inches or 0.9144 meter.
UoM- Length Size Units of Measure - {Outer Diameter}	cm {Centimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	CMT	Centimetre	A centimetre is equal to one hundredth of a metre.
UoM- Length Size Units of Measure - {Outer Diameter}	dm {Decimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	DMT	Decimetre	A decimetre is equal to one tenth of a metre.
UoM- Length Size Units of Measure - {Outer Diameter}	fm {Femtometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	A71	Femtometre	Femtometre- a quadrillionth of a metre (10 to the negative 15th power)
UoM- Length Size Units of Measure - {Outer Diameter}	km {Kilometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	KMT	Kilometre	A kilometre is one thousand (1000) metres
UoM- Length Size Units of Measure - {Outer Diameter}	m {Meter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MTR	Metre	The metre is the basic unit of length in the International System of Units (SI).

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Length Size Units of Measure - {Outer Diameter}	mm {Millimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MMT	Millimetre	A millimetre is one thousandth of a metre (0.001)
UoM- Length Size Units of Measure - {Outer Diameter}	nm {Nanometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C45	Nanometre	Nanometre- a billionth of a metre (10 to the negative 9th power)
UoM- Length Size Units of Measure - {Outer Diameter}	pm {Picometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C52	Picometre	Picometre- a trillionth of a metre (10 to the negative 12th power)
UoM- Length Size Units of Measure - {Outer Diameter}	um {Micrometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	4H	Micrometre	A micrometre is one millionth of a metre, also termed Micron.
UoM- Length Size Units of Measure - {Pore Size}	[ft_i] {Feet}		clinicalSizeValue; height; width; depth; and netContent	Dimension	FOT	Foot	The international foot is defined to be equal to 0.3048 meters.
UoM- Length Size Units of Measure - {Pore Size}	[in_i] {Inch}		clinicalSizeValue; height; width; depth; and netContent	Dimension	INH	Inches	An international inch is defined to be equal to 25.4 millimeters.
UoM- Length Size Units of Measure - {Pore Size}	[yd_i] {Yard }		clinicalSizeValue; height; width; depth; and netContent	Dimension	YRD	Yard	A yard is It is equal to 3 feet or 36 inches or 0.9144 meter.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Length Size Units of Measure - {Pore Size}	cm {Centimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	CMT	Centimetre	A centimetre is equal to one hundredth of a metre.
UoM- Length Size Units of Measure - {Pore Size}	dm {Decimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	DMT	Decimetre	A decimetre is equal to one tenth of a metre.
UoM- Length Size Units of Measure - {Pore Size}	fm {Femtometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	A71	Femtometre	Femtometre- a quadrillionth of a metre (10 to the negative 15th power)
UoM- Length Size Units of Measure - {Pore Size}	km {Kilometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	KMT	Kilometre	A kilometre is one thousand (1000) metres
UoM- Length Size Units of Measure - {Pore Size}	m {Meter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MTR	Metre	The metre is the basic unit of length in the International System of Units (SI).
UoM- Length Size Units of Measure - {Pore Size}	mm {Millimeter}		clinicalSizeValue; height; width; depth; and netContent	Dimension	MMT	Millimetre	A millimetre is one thousandth of a metre (0.001)
UoM- Length Size Units of Measure - {Pore Size}	nm {Nanometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C45	Nanometre	Nanometre- a billionth of a metre (10 to the negative 9th power)
UoM- Length Size Units of Measure - {Pore Size}	pm {Picometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	C52	Picometre	Picometre- a trillionth of a metre (10 to the negative 12th power)

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Length Size Units of Measure - {Pore Size}	um {Micrometer}		clinicalSizeValue; height; width; depth; and netContent	Dimension	4H	Micrometre	A micrometre is one millionth of a metre, also termed Micron.
UoM- Pressure Units of Measure- {Pressure }	[psi} {Pound per Square Inch}		storageEnvironmentAtmosphericPressureMaximum + UoM; storageEnvironmentAtmosphericPressureMinimum + UoM; transportationEnvironmentAtmosphericPressureMaximum + UoM; and transportationEnvironmentAtmosphericPressureMinimum + UoM	Pressure	80	Pound per square inch - Absolute	Psia (pound-force per square inch absolute)is a unit of pressure relative to a vacuum (such as that in space). At sea level, Earth's atmosphere actually exerts a pressure of 14.7 psi. Humans do not feel this pressure because internal pressure of liquid in their bodies matches the external pressure. If a pressure gauge is calibrated to read zero in space, then at sea level on Earth it would read 14.7 psi. Thus a reading of 30 psig, on Earth, on a tire gauge represents an absolute pressure of 44.7 psi (lb/in^2).
UoM- Pressure Units of Measure- {Pressure }	Hz {Hertz}		netContent	Frequency	HTZ	Hertz	A unit of frequency defined as the number of complete cycles per second; it is the basic unit of frequency in the International System of Units (SI).
UoM- Pressure Units of Measure- {Pressure }	kPa {KiloPascal}		storageEnvironmentAtmosphericPressureMaximum + UoM; storageEnvironmentAtmosphericPressureMinimum + UoM; transportationEnvironmentAtmosphericPressureMaximum + UoM; and transportationEnvironmentAtmosphericPressureMinimum + UoM	Pressure	KPA	Kilopascal	A thousand pascals (10 to the 3rd power)

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Pressure Units of Measure- {Pressure }	mbar {millibar }		storageEnvironmentAtmosphericPressureMaximum + UoM; storageEnvironmentAtmosphericPressureMinimum + UoM; transportationEnvironmentAtmosphericPressureMaximum + UoM; and transportationEnvironmentAtmosphericPressureMinimum + UoM	Pressure	MBR	Millibar	A hundred pascals (10 to the 2nd power)
UoM- Pressure Units of Measure- {Pressure }	mg/{TotalVolume} {Milligram per Total Volume}		storageEnvironmentAtmosphericPressureMaximum + UoM; storageEnvironmentAtmosphericPressureMinimum + UoM; transportationEnvironmentAtmosphericPressureMaximum + UoM; and transportationEnvironmentAtmosphericPressureMinimum + UoM	Pressure	PENDING	Currently no GDSN or UN Recommendation 20 Value for FDA GUDID UoM. A Question is posed to the FDA to clarify which volume they refer to or does it matter. If it does not matter, UN Recommendation 20 has the following to be used and a GDSN Change request would be entered to support- NA, M1, C12, H63, MF, MK, GO.	

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Pressure Units of Measure- {Pressure }	U/L {Units per Liter}		storageEnvironmentAtmosphericPressureMaximum + UoM; storageEnvironmentAtmosphericPressureMinimum + UoM; transportationEnvironmentAtmosphericPressureMaximum + UoM; and transportationEnvironmentAtmosphericPressureMinimum + UoM	Pressure	PENDING	Currently no GDSN or UN Recommendation 20 Value for FDA GUDID UoM. A Question is posed to the FDA to clarify which unit they refer to.	
UoM- Pressure Units of Measure- {Pressure }	ug/{TotalVolume} {Microgram per Total Volume}		storageEnvironmentAtmosphericPressureMaximum + UoM; storageEnvironmentAtmosphericPressureMinimum + UoM; transportationEnvironmentAtmosphericPressureMaximum + UoM; and transportationEnvironmentAtmosphericPressureMinimum + UoM	Pressure	PENDING	Currently no GDSN or UN Recommendation 20 Value for FDA GUDID UoM. A Question is posed to the FDA to clarify which volume trey refer to or does it matter. If it does not matter, UN Recommendation 20 has the following to be used and a GDSN Change request would be entered to support- GQ, H29, J33, J34, J35, MC.	

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Storage and Handling Units of Measure - {Handling Environment Atmospheric Pressure}	[degf] {Degrees Fahrenheit}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	FAH	Degree Fahrenheit	The Fahrenheit temperature scale, the freezing point of water is 32 degrees Fahrenheit (°F) and the boiling point 212 °F (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 180 degrees apart.
UoM- Storage and Handling Units of Measure - {Handling Environment Atmospheric Pressure}	Cel {Degrees Celsius}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	CEL	Degree Celsius	Celsius (also historically known as centigrade) is a temperature scale, the freezing point of water is 0 degrees Celsius (°C) and the boiling point 100 °C (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 100 degrees apart.
UoM- Storage and Handling Units of Measure - {Handling Environment Atmospheric Pressure}	K {Degrees Kelvin}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	KEL	Kelvin	Kelvin: a unit of absolute temperature equal to 1/273.16 of the absolute temperature of the triple point of water. One kelvin degree is equal to one Celsius degree.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Storage and Handling Units of Measure - {Handling Environment Atmospheric Pressure}	kPa {KiloPascal}		storageEnvironmentAtmosphericPressureMaximum + UoM; storageEnvironmentAtmosphericPressureMinimum + UoM; transportationEnvironmentAtmosphericPressureMaximum + UoM; and transportationEnvironmentAtmosphericPressureMinimum + UoM	Pressure	KPA	Kilopascal	A thousand pascals (10 to the 3rd power)
UoM- Storage and Handling Units of Measure - {Handling Environment Atmospheric Pressure}	Percent {Percent (%) Relative Humidity}		storageHandlingHumidityMaximum + UoM; storageHandlingHumidityMinimum + UoM; transportationHumidityMaximum + UoM; and transportationHumidityMinimum + UoM	Proportion	P1	Percent	A unit of proportion equal to 0.01.
UoM- Storage and Handling Units of Measure - {Handling Environment Humidity}	[degf} {Degrees Fahrenheit}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	FAH	Degree Fahrenheit	The Fahrenheit temperature scale, the freezing point of water is 32 degrees Fahrenheit (°F) and the boiling point 212 °F (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 180 degrees apart.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Storage and Handling Units of Measure - {Handling Environment Humidity}	Cel {Degrees Celsius}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	CEL	Degree Celsius	Celsius (also historically known as centigrade) is a temperature scale, the freezing point of water is 0 degrees Celsius (°C) and the boiling point 100 °C (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 100 degrees apart.
UoM- Storage and Handling Units of Measure - {Handling Environment Humidity}	K {Degrees Kelvin}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	KEL	Kelvin	Kelvin: a unit of absolute temperature equal to 1/273.16 of the absolute temperature of the triple point of water. One kelvin degree is equal to one Celsius degree.
UoM- Storage and Handling Units of Measure - {Handling Environment Humidity}	kPa {KiloPascal}		storageEnvironmentAtmosphericPressureMaximum + UoM; storageEnvironmentAtmosphericPressureMinimum + UoM; transportationEnvironmentAtmosphericPressureMaximum + UoM; and transportationEnvironmentAtmosphericPressureMinimum + UoM	Pressure	KPA	Kilopascal	A thousand pascals (10 to the 3rd power)

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Storage and Handling Units of Measure - {Handling Environment Humidity}	Percent {Percent (%) Relative Humidity}		storageHandlingHumidityMaximum + UoM; storageHandlingHumidityMinimum + UoM; transportationHumidityMaximum + UoM; and transportationHumidityMinimum + UoM	Proportion	P1	Percent	A unit of proportion equal to 0.01.
UoM- Storage and Handling Units of Measure - {Handling Environment Temperature}	[degf} {Degrees Fahrenheit}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	FAH	Degree Fahrenheit	The Fahrenheit temperature scale, the freezing point of water is 32 degrees Fahrenheit (°F) and the boiling point 212 °F (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 180 degrees apart.
UoM- Storage and Handling Units of Measure - {Handling Environment Temperature}	Cel {Degrees Celsius}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	CEL	Degree Celsius	Celsius (also historically known as centigrade) is a temperature scale, the freezing point of water is 0 degrees Celsius (°C) and the boiling point 100 °C (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 100 degrees apart.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Storage and Handling Units of Measure - {Handling Environment Temperature}	K {Degrees Kelvin}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	KEL	Kelvin	Kelvin: a unit of absolute temperature equal to 1/273.16 of the absolute temperature of the triple point of water. One kelvin degree is equal to one Celsius degree.
UoM- Storage and Handling Units of Measure - {Handling Environment Temperature}	kPa {KiloPascal}		storageEnvironmentAtmosphericPressureMaximum + UoM; storageEnvironmentAtmosphericPressureMinimum + UoM; transportationEnvironmentAtmosphericPressureMaximum + UoM; and transportationEnvironmentAtmosphericPressureMinimum + UoM	Pressure	KPA	Kilopascal	A thousand pascals (10 to the 3rd power)
UoM- Storage and Handling Units of Measure - {Handling Environment Temperature}	Percent {Percent (%) Relative Humidity}		storageHandlingHumidityMaximum + UoM; storageHandlingHumidityMinimum + UoM; transportationHumidityMaximum + UoM; and transportationHumidityMinimum + UoM	Proportion	P1	Percent	A unit of proportion equal to 0.01.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Storage and Handling Units of Measure - {Storage Environment Atmospheric Pressure}	[degf] {Degrees Fahrenheit}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	FAH	Degree Fahrenheit	The Fahrenheit temperature scale, the freezing point of water is 32 degrees Fahrenheit (°F) and the boiling point 212 °F (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 180 degrees apart.
UoM- Storage and Handling Units of Measure - {Storage Environment Atmospheric Pressure}	Cel {Degrees Celsius}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	CEL	Degree Celsius	Celsius (also historically known as centigrade) is a temperature scale, the freezing point of water is 0 degrees Celsius (°C) and the boiling point 100 °C (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 100 degrees apart.
UoM- Storage and Handling Units of Measure - {Storage Environment Atmospheric Pressure}	K {Degrees Kelvin}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	KEL	Kelvin	Kelvin: a unit of absolute temperature equal to 1/273.16 of the absolute temperature of the triple point of water. One kelvin degree is equal to one Celsius degree.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Storage and Handling Units of Measure - {Storage Environment Atmospheric Pressure}	kPa {KiloPascal}		storageEnvironmentAtmosphericPressureMaximum + UoM; storageEnvironmentAtmosphericPressureMinimum + UoM; transportationEnvironmentAtmosphericPressureMaximum + UoM; and transportationEnvironmentAtmosphericPressureMinimum + UoM	Pressure	KPA	Kilopascal	A thousand pascals (10 to the 3rd power)
UoM- Storage and Handling Units of Measure - {Storage Environment Atmospheric Pressure}	Percent {Percent (%) Relative Humidity}		storageHandlingHumidityMaximum + UoM; storageHandlingHumidityMinimum + UoM; transportationHumidityMaximum + UoM; and transportationHumidityMinimum + UoM	Proportion	P1	Percent	A unit of proportion equal to 0.01.
UoM- Storage and Handling Units of Measure - {Storage Environment Humidity}	[degf} {Degrees Fahrenheit}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	FAH	Degree Fahrenheit	The Fahrenheit temperature scale, the freezing point of water is 32 degrees Fahrenheit (°F) and the boiling point 212 °F (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 180 degrees apart.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Storage and Handling Units of Measure - {Storage Environment Humidity}	Cel {Degrees Celsius}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	CEL	Degree Celsius	Celsius (also historically known as centigrade) is a temperature scale, the freezing point of water is 0 degrees Celsius (°C) and the boiling point 100 °C (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 100 degrees apart.
UoM- Storage and Handling Units of Measure - {Storage Environment Humidity}	K {Degrees Kelvin}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	KEL	Kelvin	Kelvin: a unit of absolute temperature equal to 1/273.16 of the absolute temperature of the triple point of water. One kelvin degree is equal to one Celsius degree.
UoM- Storage and Handling Units of Measure - {Storage Environment Humidity}	kPa {KiloPascal}		storageEnvironmentAtmosphericPressureMaximum + UoM; storageEnvironmentAtmosphericPressureMinimum + UoM; transportationEnvironmentAtmosphericPressureMaximum + UoM; and transportationEnvironmentAtmosphericPressureMinimum + UoM	Pressure	KPA	Kilopascal	A thousand pascals (10 to the 3rd power)

© 2015 GS1 AISBL

FDA GUDID Code- Attribute-Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Storage and Handling Units of Measure - {Storage Environment Humidity}	Percent {Percent (%) Relative Humidity}		storageHandlingHumidityMaximum + UoM; storageHandlingHumidityMinimum + UoM; transportationHumidityMaximum + UoM; and transportationHumidityMinimum + UoM	Proportion	P1	Percent	A unit of proportion equal to 0.01.
UoM- Storage and Handling Units of Measure - {Storage Environment Temperature}	[degf} {Degrees Fahrenheit}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	FAH	Degree Fahrenheit	The Fahrenheit temperature scale, the freezing point of water is 32 degrees Fahrenheit (°F) and the boiling point 212 °F (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 180 degrees apart.
UoM- Storage and Handling Units of Measure - {Storage Environment Temperature}	Cel {Degrees Celsius}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	CEL	Degree Celsius	Celsius (also historically known as centigrade) is a temperature scale, the freezing point of water is 0 degrees Celsius (°C) and the boiling point 100 °C (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 100 degrees apart.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Storage and Handling Units of Measure - {Storage Environment Temperature}	K {Degrees Kelvin}		storageHandlingTemperatureMaximum + UoM; storageHandlingTemperatureMinimum + UoM; transportationMaximumTemperature + UoM; and transportationMinimumTemperature + UoM	Temperature	KEL	Kelvin	Kelvin: a unit of absolute temperature equal to 1/273.16 of the absolute temperature of the triple point of water. One kelvin degree is equal to one Celsius degree.
UoM- Storage and Handling Units of Measure - {Storage Environment Temperature}	kPa {KiloPascal}		storageEnvironmentAtmosphericPressureMaximum + UoM; storageEnvironmentAtmosphericPressureMinimum + UoM; transportationEnvironmentAtmosphericPressureMaximum + UoM; and transportationEnvironmentAtmosphericPressureMinimum + UoM	Pressure	KPA	Kilopascal	A thousand pascals (10 to the 3rd power)
UoM- Storage and Handling Units of Measure - {Storage Environment Temperature}	Percent {Percent (%) Relative Humidity}		storageHandlingHumidityMaximum + UoM; storageHandlingHumidityMinimum + UoM; transportationHumidityMaximum + UoM; and transportationHumidityMinimum + UoM	Proportion	P1	Percent	A unit of proportion equal to 0.01.
UoM- Volume Units of Measure- {Total Volume}	[cin_i] {Cubic Inch}		netContent	Volume	INQ	Cubic inch	A cubic inch is the volume of a cube of side length one inch (0.254 m).

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Volume Units of Measure- {Total Volume}	[cup_us] {Cup}		netContent	Volume	CU	Cup	
UoM- Volume Units of Measure- {Total Volume}	[foz_us] {Fluid Ounce}		netContent	Volume	OZA	Fluid ounce (US)	A fluid ounce (US) is equal to one sixteenth (1/16) of a US pint or 29.5735295625 millilitres .
UoM- Volume Units of Measure- {Total Volume}	[gal_us] {Gallon}		netContent	Volume	GLL	Gallon (US)	The U.S. liquid gallon is legally defined as 231 cubic inches, and is equal to exactly 3.785411784 litres or about 0.133680555 cubic feet.
UoM- Volume Units of Measure- {Total Volume}	[pt_us] {Pint}		netContent	Volume	PTI	Pint (UK)	A pint (UK) is equal to 1/8 Gallon (UK); used primarly as a measure for beer and cider when sold by the glass.
UoM- Volume Units of Measure- {Total Volume}	[qt_us] {Quart}		netContent	Volume	QTD	Quart (US dry)	A US dry quart is equal to 1/32 of a US bushel, exactly 1.101220942715 litres.
UoM- Volume Units of Measure- {Total Volume}	cL {Centiliter}		netContent	Volume	CLT	Centilitre	A centilitre is one hundredth (1/100) of a litre
UoM- Volume Units of Measure- {Total Volume}	dL {Deciliter}		netContent	Volume	DLT	Decilitre	A decilitre is one tenth (1/10) of a litre.
UoM- Volume Units of Measure- {Total Volume}	fL {Femtoliter}		netContent	Volume	FML	Femtolitre	Femtolitre- Femtolitre is the metric unit of volume equal to one thousand trillionth (European) or one quadrillionth (American) litre. One femtolitre is the same as one cubic micrometre (?m3), , which can be represented numerically as 0.00000000000001/liter.

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Volume Units of Measure- {Total Volume}	kL {Kiloliter}		netContent	Volume	K6	Kilolitre	A kilolitre is one thousand (1000) litres.
UoM- Volume Units of Measure- {Total Volume}	L {Liter}		netContent	Volume	LTR	Litre	A litre is defined as a special name for a cubic decimetre (1 L = 1 dm3 = 103 cm3).
UoM- Volume Units of Measure- {Total Volume}	mL {Milliliter}		netContent	Volume	MLT	Millilitre	A millilitre is one thousandth of a litre (0.001)
UoM- Volume Units of Measure- {Total Volume}	nL {Nanoliter}		netContent	Volume	NAN	Nanolitre	Nanolitre is the metric unit of volume equal to one billionth of a litre, which can be represented numerically as 0.000000001/liter.
UoM- Volume Units of Measure- {Total Volume}	pL {Picoliter}		netContent	Volume	PLT	Picolitre	Picoliter is the metric unit of volume equal to a trillionth (one millionth of a millionth) of a liter, which can be represented numerically as 0.000000000001/liter. just as the prefix nano denotes a billionth part
UoM- Volume Units of Measure- {Total Volume}	uL {Microliter}		netContent	Volume	2X	Metre Per Minute	Metre Per Minute
UoM- Weight Units of Measure - {Weight}	[lb_av} {Pound}		grossWeight; and netContent	Mass	LBR	Pound	The international avoirdupois pound of exactly 0.45359237 kilogram.
UoM- Weight Units of Measure - {Weight}	[ston_av} {Ton }		grossWeight; and netContent	Mass	STN	Ton (US) or short ton (UK)	Ton (US) = 2000 Lb or 907 Kg

© 2015 GS1 AISBL

FDA GUDID Code- Attribute- Code Group	Code Value		GS1 GDSN Attribute	GS1 GDSN Code Group	Code Value	Code Name	Code Definition
UoM- Weight Units of Measure - {Weight}	g {Gram}		grossWeight; and netContent	Mass	GRM	Gram	A gram is defined as one one-thousandth of the kilogram (1×10-3 kg).
UoM- Weight Units of Measure - {Weight}	kg {Kilogram}		grossWeight; and netContent	Mass	KGM	Kilogram	A unit of mass equal to one thousand grams.
UoM- Weight Units of Measure - {Weight}	mg {Milligram }		grossWeight; and netContent	Mass	MGM	Milligram	A milligram is one thousandth of a gram (0.001)
UoM- Weight Units of Measure - {Weight}	t {Metric Ton}		grossWeight; and netContent	Mass	TNE	Tonne	Metric ton = 1000 Kg
UoM- Weight Units of Measure - {Weight}	ug {Microgram}		grossWeight; and netContent	Mass	MC	Microgram	A microgram is one millionth of a gram (0.000001)

© 2015 GS1 AISBL

6 Guidance on Populating Values

This section provides guidance on how to populate each of the GS1 GDSN attributes to meet the requirements of the FDA GUDID attribute list. The choice of attributes in this guidance is related to the GUDID to GDSN Mapping provided in section 4. The guidance is ordered accordingly in line with the order as presented from the FDA documentation.

6.1 Issuing Agency

FDA GUDID

GUDID Description	Organization accredited by FDA to operate a system for the issuance of UDIs.
GUDID Data Entry Notes	Choose a value from the drop down LOV (Webtool)
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
GUDID Required in Database?	Required
GUDID Data Type & Length	NA
GUDID Entry List of Values (LOV)	GS1, HIBCC, ICCBBA
New DI Trigger?	YES
Public/Private Status	PUBLIC

GS1 GDSN

Module	N/A
Content	N/A
Attribute/Role	N/A- LOGICAL POPUALTION
Datatype/Secondary Class	N/A
Multiplicity	N/A
Occurrence	N/A
Definition	N/A
Code List Name	N/A

Population Guidance (below)

LOGICAL POPULATION- On the outbound GUDID Message by the Data Pool. Will use the value "GS1" in all GDSN instances. By using GDSN, the GTIN of the lowest level of the hierarchy will become the Primary DI. By using a GTIN as the Primary DI, this will require the issuing agency to be GS1.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be changed. Many of the data elements are locked and can no longer be edited.

© 2015 GS1 AISBL

6.2 Primary DI#

FDA GUDID

Description	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest package level of a medical device containing a full UDI. For medical devices without packaging, the primary DI number and full UDI may be on the device itself.
Data Entry Notes	Enter the Device Identifier (DI) Number. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Required
Data Type & Length	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.
Entry List of Values (LOV)	NA
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Module	Core Item
Content	GTIN (generalization)
Attribute/Role	GTIN
Datatype/Secondary Class	TradeItemIdentification
Multiplicity	GDSN Mandatory
Occurrence	Single
Definition	Trade Item Identification for a TradeItem.
Code List Name	N/A

Population Guidance (below)

This is one of the key elements in GDSN and is required for the use of GDSN. By using GDSN to provide data to the GUDID, the lowest level GTIN will always be the Primary DI. All other issuing agency identification will be published as secondary device identifiers.

Once published, a 7-day grace period begins. During the grace period, most attribute can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

6.3 Device Count

FDA GUDID

Description	Number of medical devices in the base package.
Data Entry Notes	Enter the number of devices. Example: Base Package = Box of 100 gloves; Primary DI = 101; Device Count = 100.
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Required

© 2015 GS1 AISBL

Description	Number of medical devices in the base package.
Data Type & Length	Type: Num. Length: 7
Entry List of Values (LOV)	N/A
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN (Temporary population until final GDSN deployment)

Module	AVP
Content	
Attribute/Role	uDIDDeviceCount
Datatype/Secondary Class	Integer
Multiplicity	Optional
Occurrence	Single
Definition	The count of medical devices which are contained inside the base item for regulatory purposes.
Code List Name	N/A

Population Guidance (below)

Device count is a number. It is important to note that if the Device Count is greater than 1 (>1), then a Unit of Use DI is required to be provided in the GUDID.

Relevant examples of how to populate are:

Pack of 6 syringes, where the pack is the device (Primary DI). In this example, uDIDDeviceCount would be populated with "6" for a device count of 6.

An assay with 5 tests, where the Assay is the device (Primary DI). In this example, uDIDDeviceCount would be populated with "1" for a device count of 1. The assay can not be split apart, however netContent (for GDS Recipients) could be "5 Z52" signifying 5 uses.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

6.4 Unit of Use DI# Number

FDA GUDID

Description	An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.
Data Entry Notes	Enter the Unit of Use DI Number. Unit of Use DI is an identifier used by hospital staff and Materials Management to account for a single device when the UDI is labeled on a higher level of packaging. The Unit of Use DI does not appear on the label. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters If Device Count = 1, cannot add Unit of Use DI Number.
Edit Rules After Grace Period	Edit (Editing of entered data is allowed)
Required?	Conditionally Required* *If Device Count >1

© 2015 GS1 AISBL

Description	An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.
Data Type & Length	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.
Entry List of Values (LOV)	NA
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (requires 2 GDSN attribute to denote the GUDID Unit of Use)

Module	Core Item
Content	Attribute
Attribute/Role	componentNumber
Datatype/Secondary Class	nonNegative Integer
Multiplicity	Mandatory (If module is invoked)
Occurrence	Single
Definition	Indicate a sequence number of a component of a trade item.
Code List Name	

Module	Core Item
Content	Attribute
Attribute/Role	componentIdentification
Datatype/Secondary Class	Identifier (GTIN)
Multiplicity	Optional
Occurrence	Single
Definition	An identifier for a component.
Code List Name	N/A

Population Guidance (below)

If the Device Count is greater than 1 (>1), the unit of use DI# is required for population in the GUDID.

In GDSN, Unit of Use Dis are populated as a component of a GTIN. The first attribute componentNumber is a sequence number and would not be populated in the FDA GUDID. The second attribute componentIdentifier is the GTIN which is assigned to the Unit of Use DI.

© 2015 GS1 AISBL

6.5 Labeler DUNS Number

FDA GUDID

Description	Business number issued by Dun & Bradstreet (D&B) that is used to associate the Labeler (Company) name and address to a given version of model of a device in GUDID
Data Entry Notes	Choose appropriate DUNS Number from drop down LOV. (Webtool) To ensure data consistency for the GUDID, DUNS number submitted to the GUDID should associate to the company name that appears on the device label; ideally the address associated with the DUNS number should also match the address on the device label, but since address is not displayed to the GUDID public user, this is not a requirement for data consistency. All edits to information connected to the Labeler DUNS Number must be done through Dun & Bradstreet. No edits of DUNS information will be permitted in the GUDID.
Edit Rules After Grace Period	Edit (Editing of entered data is allowed)* *Other Labeler DUNS listed to your GUDID account can be selected. No Edit (Editing of entered data is allowed)s of DUNS info will be permitted.
Required?	Required
Data Type & Length	NA
Entry List of Values (LOV)	Labeler DUNS LOV (Webtool)
New DI Trigger?	NO
Public/Private Status	Private

GS1 GDSN *(requires 2 GDSN attribute to denote the GUDID Labeler DUNS)*

Module	PartyInRole
Content	Attribute
Attribute/Role	additionalPartyIdentification
Datatype/Secondary Class	string (Text 1-80 Characters)
Multiplicity	Mandatory (If module is invoked)
Occurrence	Single
Definition	Identification of a party by use of a code other than the Global Location Number.
Code List Name	

Module	AdditionalKeyDataTypes
Content	Attribute
Attribute/Role	additionalPartyIdentificationTypeCode
Datatype/Secondary Class	Code
Multiplicity	Mandatory (If module is invoked)
Occurrence	Single
Definition	Identification of a party by use of a code in addition to the Global Location Number.
Code List Name	AdditionalPartyIdentificationTypeCode

Population Guidance (below)

The GUDID is asking for a DUNS number for the Labeler. This value will be for the Company as listed on the label. For GDSN, the Labeler is equivalent to the Brand Owner. Brand Owner GLN is

© 2015 GS1 AISBL

a GDSN Mandatory field and the additional Party Identification attributes will be linked to the Brand Owner GLN specifically

Population of this value can be accomplished by populating the code values “DUNS” or “DUNS_PLUS_FOUR” in the GDSN attribute additionalPartyIdentificationTypeCode tied to the attribute Brand Owner GLN. The actual “DUNS” or “DUNS_PLUS_FOUR” number can then populated in the GDSN attribute AdditionalPartyIdentification. The number populated in AdditionalPartyIdentification will be populated in GUDID as the Labeler DUNS Number.

The FDA will utilise the Labeler DUNS to retrieve the company name and address from D&B. Should the FDA GUDID display an incorrect address, the Labeler must contact D&B to have necessary corrections made.

According to the FDA, the address information retrieved from D&B must match the “Manufactured By” statement on the device or its packaging. The “Manufactured By” statement refers to the entity responsible for the label, its contents and any regulatory filings. This entity may or may not be the “Manufactured At” location. The “Manufactured At” location is the actual facility or facilities where the device is produced or assembled. A device can have more than one “Manufactured At” location, but should only have one “Manufactured By” entity.

6.6 Company Name

FDA GUDID

Description	Company name associated with the labeler DUNS Number entered in the DI Record.
Data Entry Notes	Auto populated based on the Labeler DUNS Number The labeler company name submitted to the GUDID should match the company name on the device label.
Edit Rules After Grace Period	N/A (data element is not able to be changed directly; most are ‘auto-populated’ fields whose information depends on another data element).
Required?	Auto Populated
Data Type & Length	N/A
Entry List of Values (LOV)	N/A
New DI Trigger?	N/A
Public/Private Status	Public

GS1 GDSN

Module	N/A
Content	N/A
Attribute/Role	N/A
Datatype/Secondary Class	N/A
Multiplicity	N/A
Occurrence	N/A
Definition	N/A
Code List Name	N/A

Population Guidance (below)

The FDA will populate this information into the GUDID based on information from D&B based on the Labeler DUNS # provided. If the information is not correct, D&B should be contacted to facilitate correcting the data.

© 2015 GS1 AISBL

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can only be changed with Dunn and Bradstreet (D&B). Many of the data elements are locked and can no longer be edited.

6.7 Company Physical Address

FDA GUDID

Description	Company physical address associated with the labeler DUNS Number entered in the DI Record.
Data Entry Notes	Auto populated based on the Labeler DUNS Number Ideally, this address should match the labeler address as shown on the device label but since this data element is not be displayed to the GUDID public user, this is not a requirement for data consistency.
Edit Rules After Grace Period	N/A (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)
Required?	Auto Populated
Data Type & Length	N/A
Entry List of Values (LOV)	N/A
New DI Trigger?	N/A
Public/Private Status	Private

GS1 GDSN

Module	N/A
Content	N/A
Attribute/Role	N/A
Datatype/Secondary Class	N/A
Multiplicity	N/A
Occurrence	N/A
Definition	N/A
Code List Name	N/A

Population Guidance (Below)

The FDA will populate this information into the GUDID based on information from D&B based on the Labeler DUNS # provided. If the information is not correct, D&B should be contacted to facilitate correcting the data.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can only be changed with Dunn and Bradstreet (D&B). Many of the data elements are locked and can no longer be edited.

© 2015 GS1 AISBL

6.8 Brand Name

FDA GUDID

Description	The Proprietary/Trade/Brand name of the medical device as used in device labeling or in the catalog. This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. The brand name is the name that is typically registered with USPTO and have the ® and/or TM symbol
Data Entry Notes	Enter the Brand Name. Only symbols, ® and ™ will be supported for the current production release of GUDID. NOTE: per Edit Rules, you will not be able to change ® or ™ (if entered) after the Grace Period. Enter NA if the device does not have a Brand Name.
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Required
Data Type & Length	Type: Alphanum. Length: 80
Entry List of Values (LOV)	N/A
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Module	TradeItemDescriptionModule
Content	Attribute
Attribute/Role	brandName
Datatype/Secondary Class	string (Text 1-70 Characters)
Multiplicity	GDSN Mandatory
Occurrence	Single
Definition	The recognizable name used by a brand owner to uniquely identify a line of trade item or services. This is recognizable by the consumer.
Code List Name	N/A

Population Guidance (below)

This should be the most recognizable brand on the package/trade item. If there is no brand on the package/trade item, this should be the brand name under which the item is sold.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be changed. Many of the data elements are locked and can no longer be edited.

© 2015 GS1 AISBL

6.9 Version or Model

FDA GUDID

Description	The version or model found on the device label or accompanying packaging used to identify a category or design of a device. The version or model identifies all devices that have specifications, performance, size, and composition within limits set by the labeler.
Data Entry Notes	Enter the Version or Model. Version/Model can be any distinguishing string of letters and/or numbers. Catalog Number can be entered if device does not currently have a Version or Model. If the device does not have a version, model or catalog number, enter a concept that can be used to identify all devices that have specifications, performance, size, and composition within limits set by the labeler.
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Required
Data Type & Length	Type: Alphanum. Length: 40
Entry List of Values (LOV)	N/A
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN (requires 2 GDSN attribute to denote the GUDID Version or Model)

Module	AdditionalKeyDataTypes
Content	Attribute
Attribute/Role	additionalTradeItemIdentificationTypeCode
Datatype/Secondary Class	Code
Multiplicity	Mandatory (If module is invoked)
Occurrence	Single
Definition	This code will be used to cross-reference the Vendors internal trade item number to the GTIN in a one to one relationship.
Code List Name	AdditionalTradeItemIdentificationTypeCode (MODEL_NUMBER)

Module	GS1IdentificationComponents
Content	Attribute
Attribute/Role	additionalTradeItemIdentification
Datatype/Secondary Class	AdditionalTradeItemIdentification
Multiplicity	Mandatory (If module is invoked)
Occurrence	Single
Definition	Alternative means to the Global Trade Item Number to identify a trade item.
Code List Name	N/A

Population Guidance (below)

The GUDID is asking for a Model Number for the device. This can be accomplished by the population of the code value “MODEL_NUMBER” in the GDSN attribute additionalTradeItemIdentificationTypeCode. The actual Model Number can then be populated in the GUDID using the associated additionalTradeItemIdentification.

© 2015 GS1 AISBL

The code value of MODEL_NUMBER is defined as- The Additional Trade Item Identification value populated is an identification number, which defines the configuration of the product in addition to the Item number. This is typically printed or otherwise attached to an item. In electronics, this number is typically found around or near a serial number.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be changed. Many of the data elements are locked and can no longer be edited.

This group of attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Catalog Number, Secondary DI Number, DM DI Number, and FDA Listing Number.

6.10 Catalog Number

FDA GUDID

Description	The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.
Data Entry Notes	Enter the Catalog or Reference Number. Catalog/Reference number can also serve as Version/Model if it represents the devices that have specifications, performance, size, and composition within limits set by the labeler.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Optional
Data Type & Length	Type: Alphanum. Length: 40
Entry List of Values (LOV)	NA
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (requires 2 GDSN attribute to denote the GUDID Catalog Number)

Module	AdditionalKeyDataTypes
Content	Attribute
Attribute/Role	additionalTradeItemIdentificationTypeCode
Datatype/Secondary Class	Code
Multiplicity	Mandatory (If module is invoked)
Occurrence	Single
Definition	This code will be used to cross-reference the Vendors internal trade item number to the GTIN in a one to one relationship.
Code List Name	AdditionalTradeItemIdentificationTypeCode (SUPLIER_ASSIGNED)

Module	GS1IdentificationComponents
Content	Attribute
Attribute/Role	additionalTradeItemIdentification
Datatype/Secondary Class	AdditionalTradeItemIdentification
Multiplicity	Mandatory (If module is invoked)
Occurrence	Single

© 2015 GS1 AISBL

Module	GS1IdentificationComponents
Definition	Alternative means to the Global Trade Item Number to identify a trade item.
Code List Name	N/A

Population Guidance (below)

The GUDID is asking for a Catalog Number for the device. This can be accomplished by the population of the code value "SUPPLIER_ASSIGNED" in the GDSN attribute additionalTradeItemIdentificationTypeCode. The actual Catalog Number can then be populated in the GUDID using the associated additionalTradeItemIdentification.

The code value of SUPPLIER_ASSIGNED is defined as- The additional Trade Item Identification value populated has been developed and assigned by the party which provides service(s) and/or manufactures or otherwise has possession of the goods and consigns or makes them available in trade. This number is a base model or style number assigned to the product and may be the same for several GTINs where they are variations of each other. For example a coffee mug with 3 GTINs one each for the brown mug, the white mug, and the black mug might all be the supplier assigned number of AB123. Use of this value is recommended in the absence of a Model Number or Manufacturer's Part Number.

This group of attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Version or Model, Secondary DI Number, DM DI Number, and FDA Listing Number.

6.11 Device Description

FDA GUDID

Description	Additional relevant information about the device that is not already captured as a distinct GUDID data attribute.
Data Entry Notes	Enter device description. Device description should include any description found on the device label to support user comparison of the device label to the GUDID device record. Otherwise, include any additional description or text found in the device labeling.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Optional
Data Type & Length	Type: Alphanum. Length: 2000
Entry List of Values (LOV)	NA
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	TradeItemDescriptionModule
Content	Attribute
Attribute/Role	additionalTradeItemDescription
Datatype/Secondary Class	Description500 (Free Text 1-500 Characters) (Language Qualified)
Multiplicity	Optional
Occurrence	Single

© 2015 GS1 AISBL

Module	TradeItemDescriptionModule
Definition	Additional variants necessary to communicate to the industry to help define the product. Multiple variants can be established for each GTIN. This is a repeatable field, e.g. Style, Colour, and Fragrance. Allows for the representation of the same value in different languages but not for multiple values.
Code List Name	N/A

Population Guidance (below)

This description is the Labeler's description for the device.

6.12 DI Record Publish Date

FDA GUDID

Description	Indicates the date the DI Record gets published and is available via Public Search
Data Entry Notes	Choose date from calendar or manually enter date in new format (yyyy-mm-dd). This date determines the Grace Period; the 7 calendar days start the day after the DI Record Publish Date. This date should be set in the future to allow time to ensure accurate data entry. We recommend you set this date in the future, but 7 days prior to any compliance deadline. (Drop down is for Webtool only)
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Required
Data Type & Length	Type: Num. (date format) Length: 10
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (Temporary population until final GDSN deployment)

Module	AVP
Content	
Attribute/Role	uDIDPublishDate
Datatype/Secondary Class	DateTime
Multiplicity	Optional
Occurrence	Single
Definition	The date upon which the Trade Item can be published by the Unique Device Identifier Database (UDID) in their public facing systems. Until this date, the product information may reside in the UDID, but will not be visible to the public. This data is not changeable.
Code List Name	N/A

Population Guidance (below)

This attribute is a temporary attribute (AVP) in GDSN- uDIDPublishDate. It will be deployed into the GDSN Schema in 2016-17 into a final solution. The final solution will be relationship dependent which allows for a different yet specific value to be provided for each UDIDs.

This attribute can not be changed or edited once the date has been reached. For example if the date is populated as 20140920, then after 9/9/2014, this date can not be edited.

The Labeler will need to pay particular attention to this date. On this date, the device information will be published by the FDA to the public GUDID site. Once published, a 7-day grace period begins.

© 2015 GS1 AISBL

During the grace period, most attributes can be edited. After the grace period ends, on day 8, many of the data elements are locked and can no longer be edited.

If the current date is equal to or greater than the GUDID Publication Date (uDIDPublishDate in GDSN), then the GUDID attribute Commercial Distribution Status will be set to “In Commercial Distribution” automatically by the FDA.

6.13 Commercial Distribution End Date

FDA GUDID

Description	Indicates the date the device is no longer held or offered for sale. See 21 CFR 807.3(b) for exceptions. The device may or may not still be available for purchase in the marketplace.
Data Entry Notes	Choose date from calendar or manually enter date in new format (yyyy-mm-dd). (Drop down is for Webtool only)
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Optional
Data Type & Length	Type: Num. (date format) Length: 10
Entry List of Values (LOV)	NA
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	DeliveryPurchasingInformationModule
Content	Attribute
Attribute/Role	lastShipDate
Datatype/Secondary Class	DateTime
Multiplicity	Optional
Occurrence	Single
Definition	Indicates the latest date that the trade item can be shipped. This is independent of any specific ship-from location.
Code List Name	N/A

Population Guidance (below)

This date signals that a trade item will no longer be in distribution from the Labeler.

If the current date is equal to or greater than the GUDID Commercial Distribution End Date (lastShipDate in GDSN), then the GUDID attribute Commercial Distribution Status will be set to “Not in Commercial Distribution” automatically by the FDA.

© 2015 GS1 AISBL

6.14 Commercial Distribution Status

FDA GUDID

Description	Indicates whether the device is in commercial distribution as defined under 21 CFR 807.3(b)
Data Entry Notes	Auto populated based on Commercial Distribution End Date. If no Commercial Distribution End Date is entered, the status is 'In Commercial Distribution
Edit Rules After Grace Period	N/A (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)
Required?	Auto Populated
Data Type & Length	N/A
Entry List of Values (LOV)	In Commercial Distribution; Not in Commercial Distribution
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	N/A
Content	N/A
Attribute/Role	Derived by the FDA GUDID based on uDIDPublishDate and lastShipDate
Datatype/Secondary Class	N/A
Multiplicity	N/A
Occurrence	N/A
Definition	N/A
Code List Name	N/A

Population Guidance (below)

If the current date is equal to or greater than the GUDID Publication Date (uDIDPublishDate in GDSN), then the GUDID attribute Commercial Distribution Status will be set to "In Commercial Distribution" automatically by the FDA. If the current date is equal to or greater than the GUDID Commercial Distribution End Date (lastShipDate in GDSN), then the GUDID attribute Commercial Distribution Status will be set to "Not in Commercial Distribution" automatically by the FDA.

6.15 Device Subject to Direct Marking (DM), but Exempt

FDA GUDID

Description	The device is exempt from Direct Marking requirements under 21 CFR 801.45.
Data Entry Notes	Select checkbox if appropriate. (Webtool) Labeler should select the checkbox "Device Subject to Direct Marking (DM), but Exempt" only if the device: (1) is intended to be used more than once and (2) is intended to be reprocessed before each use, but also (3) meets any one of the exception criteria outlined under 21 CFR 801.45(d). If the device is not required to be directly marked under 21 CFR 801.45(a), then this box should not be checked.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Conditionally Required* *If device is subject to 801.45

© 2015 GS1 AISBL

Description	The device is exempt from Direct Marking requirements under 21 CFR 801.45.
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	NA
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (Temporary population until final GDSN deployment)

Module	AVP
Content	
Attribute/Role	isTradeItemExemptFromDirectPartMarking
Datatype/Secondary Class	Boolean
Multiplicity	Optional
Occurrence	Single
Definition	Indicator signifying the trade item is exempt from direct identification marking according to regulation or regulatory filings within the target market.
Code List Name	N/A

Population Guidance (below)

This value should default to FALSE, unless a Labeler has an exemption and specifically changes the flag to TRUE. This attribute is only used when a device is required by the FDA to carry a direct mark (UDI) on the device itself, but has been granted an exemption from the FDA. The exemption allows the item to not have a direct mark.

This attribute is a temporary attribute (AVP) in GDSN. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

6.16 DPM DI Different from Primary DI

FDA GUDID

Description	Indicates that the DM DI Number is different than the Primary DI Number.
Data Entry Notes	Select checkbox if appropriate. (Webtool)
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Conditionally Required* *If device is subject to 801.45
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	N/A
Content	N/A
Attribute/Role	LOGICAL POPULATION by the Data Pool based on value populated in another attribute
Datatype/Secondary Class	N/A

© 2015 GS1 AISBL

Module	N/A
Multiplicity	N/A
Occurrence	N/A
Definition	N/A
Code List Name	N/A

Population Guidance (below)

LOGICAL POPULATION- (Logical BOOLEAN value of “TRUE” from the population of a value of “DIRECT_PART_MARKING” in GDSN Attribute additionalTradeItemIdentificationTypeCode or any value in the AVP attribute directPartMarking). This GUDID attribute is a Boolean and as such requires a “TRUE” or “FALSE” flag as a value. If there is a value populated for the GDSN attribute combination of additionalTradeItemIdentificatonTypeCode of “DIRECT_PART_MARK”, and an associated value populated for additionalTradeItemIdentificaton, then the logical value for the GUDID is “TRUE”; OR If there is a value populated for the AVP attribute directPartMarking, then the logical value for the GUDID is “TRUE”; else this value is “FALSE”.

6.17 DPM DI Number

FDA GUDID

Description	An identifier that is marked directly on the medical device and is different than the Primary DI Number; only applicable to devices subject to Direct Marking requirements under 21 CFR 801.45.
Data Entry Notes	Enter Direct Marking DI Number. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Conditionally Required* *If device is subject to 801.45 and 'DM DI Different from Primary DI' is checked
Data Type & Length	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.
Entry List of Values (LOV)	NA
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (Temporary population until final GDSN deployment)

Module	AVP
Content	
Attribute/Role	directPartMarking
Datatype/Secondary Class	String
Multiplicity	Optional
Occurrence	Multiple
Definition	This is a number or marking placed directly on the medical device.

© 2015 GS1 AISBL

Module	AVP
Code List Name	N/A

GS1 GDSN

GS1 GDSN (Final Deployment- requires 2 GDSN attribute to denote the GUDID DM DI Number)

Module	AdditionalKeyDataTypes
Content	Attribute
Attribute/Role	additionalTradeItemIdentificationTypeCode
Datatype/Secondary Class	Code
Multiplicity	Mandatory (If module is invoked)
Occurrence	Single
Definition	This code will be used to cross-reference the Vendors internal trade item number to the GTIN in a one to one relationship.
Code List Name	AdditionalTradeItemIdentificationTypeCode (DIRECT_PART_MARK)

Module	GS1IdentificationComponents
Content	Attribute
Attribute/Role	additionalTradeItemIdentification
Datatype/Secondary Class	AdditionalTradeItemIdentification
Multiplicity	Mandatory (If module is invoked)
Occurrence	Single
Definition	Alternative means to the Global Trade Item Number to identify a trade item.
Code List Name	N/A

Population Guidance (below)

This should only be populated if:

there is a Direct Part Mark on the Device

AND

the DI# used in the Direct Part Mark is **NOT** the same as the Primary DI#

This attribute has a temporary attribute (AVP) in GDSN- directPartMarking. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

Population of the GDSN Attribute additionalTradeItemIdentificatonTypeCode with a value of “DIRECT_PART_MARK” will allow for the appropriate value to be populated in additionalTradeItemIdentificaton. This attribute pair can be repeated for as many DPM DI#s the item might have. The value populated in the GDSN attribute additionalTradeItemIdentificaton attribute and associated with the additionalTradeItemIdentificatonTypeCode of “DIRECT_PART_MARK” is what will be populated in the GUDID.

This group of attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Version or Model, Catalog Number, Secondary DI Number, and FDA Listing Number.

© 2015 GS1 AISBL

6.18 Issuing Agency

FDA GUDID

Description	Name of Secondary DI Issuing agency.
Data Entry Notes	Choose a value from the drop down LOV. (Webtool)
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Optional
Data Type & Length	N/A
Entry List of Values (LOV)	GS1; HIBCC; ICCBBA; NDC/NHRIC
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	AdditionalKeyDataTypes
Content	Attribute
Attribute/Role	additionalTradeItemIdentificationTypeCode
Datatype/Secondary Class	Code
Multiplicity	Mandatory (If module is invoked)
Occurrence	Single
Definition	This code will be used to cross-reference the Vendors internal trade item number to the GTIN in a one to one relationship.
Code List Name	AdditionalTradeItemIdentificationTypeCode (HIBCC, ICCBBA, FDA_NDC_10, FDA_NDC_11)

Population Guidance (below)

The GS1 General Specifications stipulate that a Trade Item can only have one GTIN. As the GTIN is the primary DI# for an item using GDSN to provide data to the GUDID, a GTIN can not be a Secondary DI#. However, the item might have a Secondary DI# from another issuing agency's item number standard. Using the pair of GDSN attributes additionalTradeItemIdentificatonTypeCode and additionalTradeItemIdentificaton, these other issuing agency identifiers can be provided.

Currently, there are code values for other issuing agencies which would have an associated additionalTradeItemIdentificaton provided to the GUDID. If a value is populated for additionalTradeItemIdentificaton through GDSN for an issuing agency using the attribute additionalTradeItemIdentificatonTypeCode it will be provided to the GUDID as a secondary DI. The codes available for the Secondary DI Issuing Agency are "HIBC", "ICCBBA", "FDA_NDC_10", and "FDA_NDC_11". The population of one of these additionalTradeItemIdentificatonTypeCode values will denote the appropriate issuing agency code value for GUDID.

This value is paired with the GDSN attribute additionalTradeItemIdentification. Where this attribute is populated with a value of "HIBC", "ICCBBA", "FDA_NDC_10", and "FDA_NDC_11", then the associated value populated in additionalTradeItemIdentification will be provided to the GUDID as the Secondary DI Number.

This group attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Version or Model Number, Catalog Number, DM DI Number, and FDA Listing Number.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

© 2015 GS1 AISBL

6.19 Secondary DI Number

FDA GUDID

Description	An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the primary DI. Under 21 CFR 830.40(a), only one device identifier from any particular system for the issuance of UDIs may be used to identify a particular version or model of a device.
Data Entry Notes	Enter Secondary DI Number. If your product is labeled with a UDI and barcode from more than one issuing agency (for regulatory or marketing reasons), you must choose one issuing agency system as the Primary DI and enter the other issuing agency information here, as a Secondary DI. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Optional
Data Type & Length	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	GS1IdentificationComponents
Content	Attribute
Attribute/Role	additionalTradeItemIdentification
Datatype/Secondary Class	AdditionalTradeItemIdentification
Multiplicity	Mandatory (If module is invoked)
Occurrence	Single
Definition	Alternative means to the Global Trade Item Number to identify a trade item.
Code List Name	N/A

Population Guidance

The GS1 General Specifications stipulate that a Trade Item can only have one GTIN. As the GTIN is the primary DI# for an item using GDSN to provide data to the GUDID, a GTIN can not be a Secondary DI#. However, the item might have a Secondary DI# from another issuing agency's item number standard. Using the pair of GDSN attributes additionalTradeItemIdentificatonTypeCode and additionalTradeItemIdentificaton, these other issuing agency identifiers can be provided.

Currently, there are code values for other issuing agencies which would have an associated additionalTradeItemIdentificaton provided to the GUDID. If a value is populated for additionalTradeItemIdentificaton through GDSN for an issuing agency using the attribute additionalTradeItemIdentificatonTypeCode it will be provided to the GUDID as a secondary DI. The codes available for the Secondary DI Issuing Agency are "HIBC", "ICCBBA", "FDA_NDC_10", and "FDA_NDC_11". The population of one of these additionalTradeItemIdentificatonTypeCode values will denote the appropriate issuing agency code value for GUDID.

© 2015 GS1 AISBL

This value is paired with the GDSN attribute additionalTradeItemIdentificationTypeCode. Where this attribute is populated with a value of “HIBC”, “ICCBBA”, “FDA_NDC_10”, and “FDA_NDC_11”, then the associated value populated in additionalTradeItemIdentification will be provided to the GUDID as the Secondary DI Number.

This group attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Version or Model Number, Catalog Number, DM DI Number, and FDA Listing Number.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

6.20 Package DI Number

FDA GUDID

Description	A device identifier for the package configuration that contains multiple units of the base package (does not include shipping containers).
Data Entry Notes	Enter Package DI Number. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters Examples: Box of Gloves = DI 101 4 Boxes of Gloves (DI 101) in a Carton = Package DI 201 (the UDI on the Carton) 5 Cartons (Pkg DI 201) in a Case = Package DI 301 (the UDI on the Case) 10 Boxes of Gloves (DI 101) in a Carton = Package DI 202 (the UDI on the Carton)
Edit Rules After Grace Period	Add (Addition of new data is allowed)
Required?	Conditionally Required* *If device is available in higher levels of packaging
Data Type & Length	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (requires 2 GDSN attribute to denote the GUDID Package DI Number)

Module	GS1IdentificationComponents
Content	Attribute
Attribute/Role	gtin
Datatype/Secondary Class	GTIN
Multiplicity	GDSN Mandatory
Occurrence	Single
Definition	Global Trade Item Number (GTIN), the GS1 key used for the identification of trade items.
Code List Name	N/A

© 2015 GS1 AISBL

Module	Core Item
Content	Attribute
Attribute/Role	tradeItemUnitDescriptorCode
Datatype/Secondary Class	Code
Multiplicity	GDSN Mandatory
Occurrence	Single
Definition	Describes the hierarchical level of the trade item. TradeItemUnitIndicator is mandatory. Examples: "CASE" , "PALLET"
Code List Name	TradeItemUnitDescriptorCode (values other than "BASE_UNIT_OR_EACH")

Population Guidance (below)

The GUDID Package attributes are populated as a group and can not be entered as single elements in the message. These attributes are:

- Package DI Number
- Quantity per Package
- Contains DI Package
- Package Type
- Package Discontinue Date

All packages must be entered. If a new package level is created, it is to be added to the GUDID as part of the Primary DI to which it is applicable.

This GDSN attribute references a GTIN in the hierarchy above the primary DI. This would be, or is one of, the "parent(s)" of the primary DI. These "parents" are identified by their own GTIN (and GDSN Message). They are linked together through the use of the parent child relationship.

Population of the GUDID values for the package information will be based on any value populated in the GDSN attribute tradeItemUnitDescriptor with the exception of "BASE_UNIT_OR_EACH". The GTIN with a tradeItemUnitDescriptor value of "BASE_UNIT_OR_EACH" will always be a Primary DI for the GUDID.

See the examples below.

In GDSN, the following is provided.

Hierarchy Number 1

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
2061414111111c	CASE	1061414111111c	5	5 cartons in a case
1061414111111c	PACK_OR_INNER_PACK	0061414111111c	4	4 boxes in a carton
0061414111111c	BASE_UNIT_OR_EACH	N/A	N/A	1 Box of Gloves

Hierarchy Number 2

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
4061414111111c	CASE	3061414111111c	2	2 cartons in a case

© 2015 GS1 AISBL

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
3061414111111c	PACK_OR_INNER_PACK	0061414111111c	10	10 boxes in a carton
0061414111111c	BASE_UNIT_OR_EACH	N/A	N/A	1 Box of Gloves

This is converted to the following for population in the GUDID. On the GUDID record for Primary DI # 0061414111111c.

Package DI Number	Quantity per package	Contains DI Package	Notes
1061414111111c	4	0061414111111c	Indicates there are 4 eaches in the pack
2061414111111c	5	3061414111111c	Indicates there are 5 packs in the case
3061414111111c	10	0061414111111c	Indicates there are 10 eaches in the pack
4061414111111c	2	3061414111111c	Indicates there are 2 packs in the case

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be deleted.

6.21 Quantity per package

FDA GUDID

Description	The number of packages with a unique primary DI within a given packaging configuration.
Data Entry Notes	Enter the number of devices per package. The quantity of a package configuration must be >1. Examples: Package – Carton, Pkg DI 201 contains 4 boxes of DI 101; the quantity per package is 4. Package – Case, Pkg DI 301 contains 5 cartons of Pkg DI 201; the quantity per package is 5. Package – Carton, Pkg DI 202 contains 10 boxes of DI 101; the quantity per package is 10.
Edit Rules After Grace Period	Add (Addition of new data is allowed)
Required?	Conditionally Required* *If Package DI is entered
Data Type & Length	Type: Num. Length: 9
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	Core Item
Content	Attribute

© 2015 GS1 AISBL

Module	Core Item
Attribute/Role	quantityOfNextLowerLevelTradeItem
Datatype/Secondary Class	nonNegative Integer
Multiplicity	GDSN Dependent
Occurrence	Single
Definition	The number of one child trade item (as identified by the association of ChildTradeItem class to TradeItemIdentification class) contained by the parent trade item. The child trade item must be in the hierarchy level immediately below the parent trade item.
Code List Name	N/A

Population Guidance (below)

The GUDID Package attributes are populated as a group and can not be entered as single elements in the message. These attributes are:

- Package DI Number
- Quantity per Package
- Contains DI Package
- Package Type
- Package Discontinue Date

All packages must be entered. If a new package level is created, it is to be added to the GUDID as part of the Primary DI to which it is applicable.

This GDSN attribute references a GTIN in the hierarchy above the primary DI. This would be, or is one of, the “parent(s)” of the primary DI. These “parents” are identified by their own GTIN (and GDSN Message). They are linked together through the use of the parent child relationship.

Population of the GUDID values for the package information will be based on any value populated in the GDSN attribute tradeItemUnitDescriptor with the exception of “BASE_UNIT_OR_EACH”. The GTIN with a tradeItemUnitDescriptor value of “BASE_UNIT_OR_EACH” will always be a Primary DI for the GUDID.

See the examples below.

In GDSN, the following is provided.

Hierarchy Number 1

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
2061414111111c	CASE	1061414111111c	5	5 cartons in a case
1061414111111c	PACK_OR_INNER_PACK	0061414111111c	4	4 boxes in a carton
0061414111111c	BASE_UNIT_OR_EACH	N/A	N/A	1 Box of Gloves

Hierarchy Number 2

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
4061414111111c	CASE	3061414111111c	2	2 cartons in a case

© 2015 GS1 AISBL

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
3061414111111c	PACK_OR_INNER_PACK	0061414111111c	10	10 boxes in a carton
0061414111111c	BASE_UNIT_OR_EACH	N/A	N/A	1 Box of Gloves

This is converted to the following for population in the GUDID.

Package DI Number	Quantity per package	Contains DI Package	Notes
1061414111111c	4	0061414111111c	Indicates there are 4 eaches in the pack
2061414111111c	5	3061414111111c	Indicates there are 5 packs in the case
3061414111111c	10	0061414111111c	Indicates there are 10 eaches in the pack
4061414111111c	2	3061414111111c	Indicates there are 2 packs in the case

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be deleted.

6.22 Contains DI Package

FDA GUDID

Description	The Primary DI for the base package or the Package DI for any lower level package configuration contained within a given package configuration.
Data Entry Notes	Choose a value from the drop down LOV. (Webtool) Examples: Package DI 201 (Carton) contains base package DI 101 Package DI 202 (Carton) contains base package DI 101 Package DI 301 contains lower level Package DI 201 (Carton)
Edit Rules After Grace Period	Add (Addition of new data is allowed)
Required?	Conditionally Required* *If Package DI is entered
Data Type & Length	NA
Entry List of Values (LOV)	DI numbers; base package and all lower levels of packaging
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	Core Item
Content	ChildTradeItem
Attribute/Role	ChildGTIN (generalization)
Datatype/Secondary Class	gtin
Multiplicity	GDSN Mandatory

© 2015 GS1 AISBL

Module	Core Item
Occurrence	Multiple
Definition	A trade item in the item hierarchy level immediately below the parent trade item.
Code List Name	N/A

Population Guidance (below)

The GUDID Package attributes are populated as a group and can not be entered as single elements in the message. These attributes are:

- Package DI Number
- Quantity per Package
- Contains DI Package
- Package Type
- Package Discontinue Date

All packages must be entered. If a new package level is created, it is to be added to the GUDID as part of the Primary DI to which it is applicable.

This GDSN attribute references a GTIN in the hierarchy above the primary DI. This would be, or is one of, the "parent(s)" of the primary DI. These "parents" are identified by their own GTIN (and GDSN Message). They are linked together through the use of the parent child relationship.

Population of the GUDID values for the package information will be based on any value populated in the GDSN attribute tradeItemUnitDescriptor with the exception of "BASE_UNIT_OR_EACH". The GTIN with a tradeItemUnitDescriptor value of "BASE_UNIT_OR_EACH" will always be a Primary DI for the GUDID.

See the examples below.

In GDSN, the following is provided.

Hierarchy Number 1

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
20614141111111c	CASE	10614141111111c	5	5 cartons in a case
10614141111111c	PACK_OR_INNER_PACK	00614141111111c	4	4 boxes in a carton
00614141111111c	BASE_UNIT_OR_EACH	N/A	N/A	1 Box of Gloves

Hierarchy Number 2

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
40614141111111c	CASE	30614141111111c	2	2 cartons in a case
30614141111111c	PACK_OR_INNER_PACK	00614141111111c	10	10 boxes in a carton
00614141111111c	BASE_UNIT_OR_EACH	N/A	N/A	1 Box of Gloves

© 2015 GS1 AISBL

This is converted to the following for population in the GUDID.

Package DI Number	Quantity per package	Contains DI Package	Notes
1061414111111c	4	0061414111111c	Indicates there are 4 eaches in the pack
2061414111111c	5	3061414111111c	Indicates there are 5 packs in the case
3061414111111c	10	0061414111111c	Indicates there are 10 eaches in the pack
4061414111111c	2	3061414111111c	Indicates there are 2 packs in the case

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be deleted.

6.23 Package Type

FDA GUDID

Description	Text to describe the outer packaging of the product and enables users to understand higher level packaging configurations.
Data Entry Notes	Enter name or description of package. This field is free text. There is no implied definition or standard quantity to any package name
Edit Rules After Grace Period	Add (Addition of new data is allowed)
Required?	Optional
Data Type & Length	Type: Alphanum
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Private

GS1 GDSN

Module	PackagingInformationModule
Content	Attribute
Attribute/Role	packagingTypeCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Single
Definition	The dominant means used to transport, store, handle or display the trade item as defined by the data source. This packaging is not used to describe any manufacturing process. Data recipients can use this data for: • Space Planning • Data Accuracy (Tolerances) • Supply Chain processes • Recycling process (In combination with packaging materials) • Product buying/procurement decisions • Tax calculations/fees/duties calculation
Code List Name	PackageTypeCode

Population Guidance (below)

The GDSN attribute is a code list and is mapped to the values needed for the GUDID. In GDSN the packaging type code is a 3 character code to identify the type of packaging used for the globalTradeItemNumber. In this case, this value refers to the globalTradeItemNumber which is being used to populate the GUDID Package DI Number. The GUDID is asking for a descriptive term

 © 2015 GS1 AISBL

and not the code. There is a mapping list from which the data pools can populate the appropriate descriptive term to publish to the GUDID in section 6 of this document.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be deleted.

6.24 Package Discontinue Date

FDA GUDID

Description	Indicates the date this particular package configuration is discontinued by the Labeler
Data Entry Notes	Choose date from calendar or manually enter in format (yyyy-mm-dd). Discontinuation of a package is directly related to the discontinuation of the primary DI of the base package. However, a package can also be discontinued without the discontinuation of the base package.
Edit Rules After Grace Period	Add (Addition of new data is allowed)
Required?	Conditionally Required* *If Package DI Number and Commercial Distribution End Date are entered, must also enter Package Discontinue Date
Data Type & Length	Type: Num. (date format) Length: 10
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	TradeItemSynchronisationDates
Content	Attribute
Attribute/Role	discontinuedDateTime
Datatype/Secondary Class	DateTime
Multiplicity	Optional
Occurrence	Single
Definition	Communicates the date on which the trade item is no longer to be manufactured.
Code List Name	N/A

Population Guidance (below)

This attribute is populated from the globalTradeItemNumber record which is being used to populate the GUDID Package DI Number. This date is the date when the Package DI has been discontinued or removed from the marketplace.

If the Primary DI has reached its lastShipDate, then any Package DI attached to the Primary DI will need to have a discontinueDate populated. This ensures that a Package is not in commercial distribution when the contents of the package are not in commercial distribution. However, a Package DI can be not in commercial distribution when the contents of the package are in commercial distribution.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be deleted.

© 2015 GS1 AISBL

6.25 Package Status

FDA GUDID

Description	Indicates whether the package is in commercial distribution as defined under 21 CFR 807.3(b).
Data Entry Notes	Auto populated based on Package Discontinue Date. If Package DI and related elements are entered and no Package Distribution End Date is entered, the status is 'In Commercial Distribution.'
Edit Rules After Grace Period	NA (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)
Required?	Auto Populated
Data Type & Length	N/A
Entry List of Values (LOV)	In Commercial Distribution; Not in Commercial Distribution
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	N/A
Content	N/A
Attribute/Role	Derived by the FDA GUDID based on the Package DI's discontinuedDateTime
Datatype/Secondary Class	N/A
Multiplicity	N/A
Occurrence	N/A
Definition	N/A
Code List Name	N/A

Population Guidance (below)

If the current date is equal to or greater than the GUDID Publication Date (effectiveDate in GDSN) of the Primary DI, then the Package Status will be set to "In Commercial Distribution" automatically by the FDA. If the current date is equal to or greater than the GUDID Package Discontinue Date (discontinuedDateTime for the package level GTIN in GDSN), then the Package Status will be set to "Not in Commercial Distribution" automatically by the FDA. Note, if the Commercial Distribution Status of the Primary DI is set to "Not in Commercial Distribution", the Package Status will also be set to "Not in Commercial Distribution".

6.26 Customer Contact Phone

FDA GUDID

Description	Phone number for the customer contact; to be used by patients and consumers for device-related questions.
Data Entry Notes	Enter phone number. For North American numbers, type 10-digit number with or without punctuation. For international numbers, start with "+" and type number without punctuation. This phone number could be the 1-800 number that appears on the device labeling or the company website. Labelers can identify a Customer Contact phone number and Customer Contact email address for each device record. If an email is entered and you don't have a Customer Contact phone number, please enter '9999999999'

© 2015 GS1 AISBL

Description	Phone number for the customer contact; to be used by patients and consumers for device-related questions.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Conditionally Required* *ONLY required if Customer Contact Phone is entered
Data Type & Length	Type: Num. Length: 10 (North American numbers); 20 (all others)
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (requires 3 GDSN attributes to denote the GUDID Customer Contact Phone)

Module	TradeItemContactInformation
Content	Attribute
Attribute/Role	contactTypeCode
Datatype/Secondary Class	Code
Multiplicity	Mandatory (if Module invoked)
Occurrence	Single
Definition	The general category of the contact party for a trade item for example Purchasing.
Code List Name	ContactTypeCode (CONSUMER_SUPPORT)

Module	CommunicationChannel
Content	Attribute
Attribute/Role	communicationChannelCode
Datatype/Secondary Class	Code
Multiplicity	Mandatory (if Module invoked)
Occurrence	Single
Definition	Code specifying the type of communication channel, for example TELEPHONE.
Code List Name	CommunicationChannelCode (TELEPHONE)

Module	CommunicationChannel
Content	Attribute
Attribute/Role	communicationChannelValue
Datatype/Secondary Class	String (Text 1-200 Characters)
Multiplicity	Mandatory (if Module invoked)
Occurrence	Single
Definition	Text identifying the endpoint for the communication channel, for example a telephone number or an e-mail address.
Code List Name	N/A

© 2015 GS1 AISBL

Population Guidance (below)

The GDSN attribute contactType signifies which type of contact information is being provided. The GDSN attributes communicationChannelCode and communicationChannelValue can repeat as a pair of attributes for a single contactType. There can be more than one contactType populated for a single Trade item.

For the GUDID, the contactType of "CONSUMER_SUPPORT" will signify the information to be provided to the GUDID via GDSN. Where an instance of the GDSN attribute communicationChannelCode is populated with the value of "TELEPHONE", the corresponding communicationChannelValue will map to the GUDID attribute Customer Contact Phone.

This group attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Customer Contact Phone and Customer Contact Email.

6.27 Customer Contact Email

FDA GUDID

Description	Email for the Customer contact; to be used by patients and consumers for device-related questions
Data Entry Notes	Enter email address. This email address could be the same one that appears on the device labeling or the company website. Labelers can identify a Customer Contact email and a Customer Contact phone number for each device record. If a phone number is entered and you don't have a Customer Contact email, please enter 'xx@xx.xx'
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Conditionally Required* *ONLY required if Customer Contact Email is entered
Data Type & Length	Type: Alphanum. Length: 100
Entry List of Values (LOV)	NA
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (requires 3 GDSN attributes to denote the GUDID Customer Contact Email)

Module	TradeItemContactInformation
Content	Attribute
Attribute/Role	contactTypeCode
Datatype/Secondary Class	Code
Multiplicity	Mandatory (if Module invoked)
Occurrence	Single
Definition	The general category of the contact party for a trade item for example Purchasing.
Code List Name	ContactTypeCode (CONSUMER_SUPPORT)

Module	CommunicationChannel
Content	Attribute
Attribute/Role	communicationChannelCode

© 2015 GS1 AISBL

Module	CommunicationChannel
Datatype/Secondary Class	Code
Multiplicity	Mandatory (if Module invoked)
Occurrence	Single
Definition	Code specifying the type of communication channel, for example TELEPHONE.
Code List Name	CommunicationChannelCode (TELEPHONE)

Module	CommunicationChannel
Content	Attribute
Attribute/Role	communicationChannelValue
Datatype/Secondary Class	String (Text 1-200 Characters)
Multiplicity	Mandatory (if Module invoked)
Occurrence	Single
Definition	Text identifying the endpoint for the communication channel, for example a telephone number or an e-mail address.
Code List Name	N/A

Population Guidance (below)

The GDSN attribute contactType signifies which type of contact information is being provided. The GDSN attributes communicationChannelCode and communicationChannelValue can repeat as a pair of attributes for a single contactType. There can be more than one contactType populated for a single Trade item.

For the GUDID, the contactType of “CONSUMER_SUPPORT” will signify the information to be provided to the GUDID via GDSN. Where an instance of the GDSN attribute communicationChannelCode is populated with the value of “TELEPHONE”, the corresponding communicationChannelValue will map to the GUDID attribute Customer Contact Phone.

This group attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Customer Contact Phone and Customer Contact Email.

6.28 Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)

FDA GUDID

Description	Indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3.
Data Entry Notes	Data Entry Notes Select checkbox if DI record is for a product defined under 21 CFR 1271.3 If checked, the labeler must assign and label each HCT/P device with a distinct identification code, per 21 CFR 1271.290(c). The distinct identification code may take the form of a Donation Identification Number (DIN) , serial number, lot number, or a combination of these production identifiers (PIs). Labelers of HCT/Ps regulated as medical devices should select the appropriate type of PI that appears on the label of the device.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Optional If no data is provided, 'No' is stored

© 2015 GS1 AISBL

Description	Indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3.
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	AVP
Content	
Attribute/Role	doesTradeItemContainHumanTissue
Datatype/Secondary Class	Boolean
Multiplicity	Optional
Occurrence	Single
Definition	The trade item has, as a component or ingredient, human tissue. The amount of tissue is not limited to a certain amount, any amount will cause a flag of TRUE.
Code List Name	N/A

Population Guidance (below)

This Boolean attribute should be populated with a value of “TRUE” when there is any amount of human tissue as part of the device. Otherwise the value should default to FALSE.

6.29 Kit

FDA GUDID

Description	Indicates that the device is a convenience, combination, in vitro diagnostic (IVD), or medical procedure kit. Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and is being distributed as a medical device.
Data Entry Notes	Select checkbox if DI record is for a kit. Do not check if the device is a constituent part of a kit. (Webtool)
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Optional
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	N/A
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN (Temporary population until final GDSN deployment)

Module	AVP
Content	
Attribute/Role	groupedProduct
Datatype/Secondary Class	Code
Multiplicity	Optional

© 2015 GS1 AISBL

Module	AVP
Occurrence	Single
Definition	Code representing if the trade item is considered by the manufacturer to be more than a single item, such as a kit, combination item.
Code List Name	GroupedProductCode (KIT or KIT_AND_COMBINATION)

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- groupedProduct. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

The GDSN attribute groupedProduct is a code list attribute. It is used to specify if an item is a kit or a combination product. A value populated for the GDSN attribute groupedProduct of “KIT” or “KIT_AND_COMBINATION” will populate a value of “TRUE” for the GUDID attribute Kit. Any other value, or when no value is provided, for the GDSN attribute will populate a value of “FALSE” for the GUDID attribute Kit.

This attribute will be used to provide several sets of information and as such may be repeated. GUDID attributes using this attribute are Kit and Combination Products.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

6.30 Combination Product

FDA GUDID

Description	Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity; packaged together as a single package; or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the products in the combination product must be a device in this case.
Data Entry Notes	Check box if DI record is for the combination product itself. Do not check if the product is a constituent part of a combination product. (Webtool)
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Optional
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	NA
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN (Temporary population until final GDSN deployment)

Module	AVP
Content	
Attribute/Role	groupedProduct
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Single
Definition	Code representing if the trade item is considered by the manufacturer to be more than a single item, such as a kit, combination item.
Code List Name	GroupedProductCode (COMBINATION or KIT_AND_COMBINATION)

© 2015 GS1 AISBL

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- groupedProduct. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

The GDSN attribute groupedProduct is a code list attribute. It is used to specify if an item is a kit or a combination product. A value populated for the GDSN attribute groupedProduct of “COMBINATION” or “KIT_AND_COMBINATION” will populate a value of “TRUE” for the GUDID attribute Kit. Any other value, or when no value is provided, for the GDSN attribute will populate a value of “FALSE” for the GUDID attribute Combination Product.

This attribute will be used to provide several sets of information and as such may be repeated. GUDID attributes using this attribute are Kit and Combination Products.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

6.31 Device Exempt from Premarket Authorization

FDA GUDID

Description	Device is exempt from FDA Premarket regulations; or a pre-amendment device.
Data Entry Notes	Select checkbox if FDA has by regulation exempted this device from premarket submission requirements; or for preamendment devices that are not subject to premarket submission requirements. If left unselected, a 'No' is stored and a Premarket Submission Number should be entered below.
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Conditionally Required* *Premarket Submission Number OR exempt status fulfills regulatory requirement.
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (Temporary population until final GDSN deployment)

Module	AVP
Content	
Attribute/Role	exemptFromFDAPreMarketAuthorization
Datatype/Secondary Class	Boolean
Multiplicity	Optional
Occurrence	Single
Definition	Device is exempt from FDA Premarket regulations. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act in order to obtain marketing clearance. Please note that some Class III preamendment devices may require a Class III 510(k). See "Historical Background2" for additional information.
Code List Name	N/A

© 2015 GS1 AISBL

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- exemptFromFDAPreMarketAuthorization. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

This Boolean attribute is used to denote if an item is such that is does not require a pre-market authorization from the FDA (termed an exemption). A value of "TRUE" for this GDSN attribute signifies that the item has been deemed exempt from needing this type of review. A value of "FALSE" or a "NULL" value will signify that an authorization is required for the item.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

6.32 FDA Premarket Submission Number

FDA GUDID

Description	Number associated with the regulatory decision regarding the applicant's legal right to market a medical device for the following submission types: 510(k), PMA, PDP, HDE, BLA, and NDA.
Data Entry Notes	Enter current FDA Premarket Submission Number(s). Each DI record represents a version or model of a device. For each DI record, you must submit the original premarket authorization number and the supplement number through which you obtained approval or clearance for the version or model identified in the DI record, as required by 830.310(b)(11). FDA Premarket Numbers should be verified with the FDA PMA or 510(k) database to make sure the Number represents the subject of the device record. Device records should be updated with additional numbers in the future, as needed. Example: PMA #123456 should be entered as 'P123456.'
Edit Rules After Grace Period	Add (Addition of new data is allowed)
Required?	Conditionally Required* *Premarket Submission Number OR exempt status fulfills regulatory requirement.
Data Type & Length	Type: Alphanum. Length: 8
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (requires 2 GDSN attributes to denote the GUDID FDA Premarket Submission Number)

Module	GDSNTradeItemClassification
Content	Attribute
Attribute/Role	AdditionalTradeItemClassificationSystemCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Single
Definition	The Classification System for the Additional Trade Item Classification.
Code List Name	AdditionalTradeItemClassificationCodeListCode (58)

Module	TradeItemClassification
Content	Attribute
Attribute/Role	additionalTradeItemClassificationCode

© 2015 GS1 AISBL

Module	TradeItemClassification
Datatype/Secondary Class	AdditionalTradeItemClassificationCode
Multiplicity	Optional
Occurrence	Multiple
Definition	Category code based on alternate classification schema chosen in addition to the Global Product Classification (GPC).
Code List Name	N/A

Population Guidance (below)

This set of attributes will allow for the population of a Pre-Market Submission Number for the device. This number will correlate to the scientific and regulatory review information which was created to evaluate the safety and efficacy of the device. This set of attributes is required to be provided when the value populated for the GDSN attribute exemptFromFDAPreMarketAuthorization is not "TRUE".

This set of attributes will also be used to populate several pieces of information- FDA Product Code, FDA Preferred Term Code, and GMDN. For supply chain use, this set of attributes can also provide the UNSPSC code for the device.

If there is a Supplement Number, place a colon (":") after the FDA Premarket Submission Number then add the Submission Number. Repeat these attributes and process for all applicable FDA Premarket Submission Numbers and Supplement Numbers.

For example, a device has a FDA Premarket Submission number of P369258. Over time 3 Supplements have been filed and approved 001, 002, and 004. Population of this information would look like this:

AdditionalTradeItemClassificationSystemCode	58
additionalClassificationCategoryCode	P369258:001
AdditionalTradeItemClassificationSystemCode	58
additionalClassificationCategoryCode	P369258:002
AdditionalTradeItemClassificationSystemCode	58
additionalClassificationCategoryCode	P369258:004

For example, a device has a FDA Premarket Submission Number of P147025. Over time 2 Supplements have been filed and approved 001, 002. Then a second FDA Premarket Submission Number was obtained P963074 and a subsequent Supplement was filed and approved, 001. Population of this information would look like this:

AdditionalTradeItemClassificationSystemCode	58
additionalClassificationCategoryCode	P147025:001
AdditionalTradeItemClassificationSystemCode	58
additionalClassificationCategoryCode	P147025:002
AdditionalTradeItemClassificationSystemCode	58
additionalClassificationCategoryCode	P9630074:001

The Data Pool will parse the supplement number from the FDA Premarket Submission Number and provide to the FDA GUDID in the two fields as required by the FDA.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but can not be edited or deleted.

© 2015 GS1 AISBL

6.33 Supplement

FDA GUDID

Description	Number assigned by FDA to a supplemental application for approval of a change in a medical device with an approved PMA, HDE, or PDP.
Data Entry Notes	Enter all valid Supplement Numbers. Each DI record represents a version or model of a device. For each DI record, you must submit the original premarket authorization number and the supplement number through which you obtained approval for the version or model identified in that DI record, as required by 830.310(b)(11). Although not all PMA supplements are applicable to a given model or version, if FDA approves a subsequent supplement applicable to that version or model, the GUDID DI record must be updated with that supplement number, in accordance with 21 CFR 830.330(b). 30 day notice supplements should be submitted ONLY if the 30 day notice impacts the device design specifications, or performance of the finished devices. Do not enter alpha characters. Example: Supplement 4 should be entered as 004.
Edit Rules After Grace Period	Add (Addition of new data is allowed)
Required?	Conditionally Required* *Premarket Submission Number OR exempt status fulfills regulatory requirement.
Data Type & Length	Type: Num. Length: 4
Entry List of Values (LOV)	NA
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (requires 2 GDSN attributes to denote the GUDID FDA Premarket Submission Number)

Module	GDSNTradeItemClassification
Content	Attribute
Attribute/Role	AdditionalTradeItemClassificationSystemCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Single
Definition	The Classification System for the Additional Trade Item Classification.
Code List Name	AdditionalTradeItemClassificationCodeListCode (58)

Module	TradeItemClassification
Content	Attribute
Attribute/Role	additionalTradeItemClassificationCode
Datatype/Secondary Class	AdditionalTradeItemClassificationCode
Multiplicity	Optional
Occurrence	Multiple
Definition	Category code based on alternate classification schema chosen in addition to the Global Product Classification (GPC).
Code List Name	N/A

© 2015 GS1 AISBL

Population Guidance (below)

This set of attributes will allow for the population of a Pre-Market Submission Number for the device. This number will correlate to the scientific and regulatory review information which was created to evaluate the safety and efficacy of the device. This set of attributes is required to be provided when the value populated for the GDSN attribute exemptFromFDAPreMarketAuthorization is not "TRUE".

This set of attributes will also be used to populate several pieces of information- FDA Product Code, FDA Preferred Term Code, and GMDN. For supply chain use, this set of attributes can also provide the UNSPSC code for the device.

If there is a Supplement Number, place a colon (":") after the FDA Premarket Submission Number then add the Submission Number. Repeat these attributes and process for all applicable FDA Premarket Submission Numbers and Supplement Numbers.

For example, a device has a FDA Premarket Submission number of P369258. Over time 3 Supplements have been filed and approved 001, 002, and 004. Population of this information would look like this:

AdditionalTradeItemClassificationSystemCode	58
additionalClassificationCategoryCode	P369258:001
AdditionalTradeItemClassificationSystemCode	58
additionalClassificationCategoryCode	P369258:002
AdditionalTradeItemClassificationSystemCode	58
additionalClassificationCategoryCode	P369258:004

For example, a device has a FDA Premarket Submission Number of P147025. Over time 2 Supplements have been filed and approved 001, 002. Then a second FDA Premarket Submission Number was obtained P963074 and a subsequent Supplement was filed and approved, 001. Population of this information would look like this:

AdditionalTradeItemClassificationSystemCode	58
additionalClassificationCategoryCode	P147025:001
AdditionalTradeItemClassificationSystemCode	58
additionalClassificationCategoryCode	P147025:002
AdditionalTradeItemClassificationSystemCode	58
additionalClassificationCategoryCode	P9630074:001

The Data Pool will parse the supplement number from the FDA Premarket Submission Number and provide to the FDA GUDID in the two fields as required by the FDA.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but can not be edited or deleted.

6.34 Product Code

FDA GUDID

Description	Classification for devices issued by the FDA.
Data Entry Notes	Enter all applicable Product Codes, three-letter code. For all PMA and 510k devices, Product Codes are assigned in the FDA approval or clearance letter, respectively. For Class I and exempt devices, the device Product Code may be self-identified.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)

© 2015 GS1 AISBL

Description	Classification for devices issued by the FDA.
Required?	Conditionally Required* *Unless device is a kit or IVD with a BL premarket submission number
Data Type & Length	Type: Alpha Legnth3
Entry List of Values (LOV)	FDA Product Code list
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (requires 2 GDSN attributes to denote the GUDID Product Code)

Module	GDSNTradeItemClassification
Content	Attribute
Attribute/Role	AdditionalTradeItemClassificationSystemCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Single
Definition	The Classification System for the Additional Trade Item Classification.
Code List Name	AdditionalTradeItemClassificationCodeListCode (43)

Module	TradeItemClassification
Content	Attribute
Attribute/Role	additionalTradeItemClassificationCode
Datatype/Secondary Class	AdditionalTradeItemClassificationCode
Multiplicity	Optional
Occurrence	Multiple
Definition	Category code based on alternate classification schema chosen in addition to the Global Product Classification (GPC).
Code List Name	N/A

Population Guidance (below)

This repeatable set of attributes will allow for the population of a FDA Product Code for the device. This can be accomplished by the population of the code value “43” in the GDSN attribute AdditionalTradeItemClassificationSystemCode . The actual Product Code can then be populated using the associated value in the GDSN attribute additionalTradeItemClassificationCode .

This set of attributes will also be used to populate several pieces of information- FDA Product Code, FDA Premarket Submission Number, FDA Preferred Term Code, and GMDN. For supply chain use, this set of attributes can also provide the UNSPSC codes for the device.

6.35 Product Code Name

FDA GUDID

Description	Name associated with the three-letter Product Code.
Data Entry Notes	Auto populated based on 3-letter Product Code
Edit Rules After Grace Period	NA (data element is not able to be changed directly; most are ‘auto-populated’ fields whose information depends on another data element)

© 2015 GS1 AISBL

Description	Name associated with the three-letter Product Code.
Required?	Auto Populated
Data Type & Length	N/A
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	N/A
Content	N/A
Attribute/Role	Auto Populated by FDA for the GUDID based on the Product Code
Datatype/Secondary Class	N/A
Multiplicity	N/A
Occurrence	N/A
Definition	N/A
Code List Name	N/A

Population Guidance (below)

The FDA will automatically populate the GUDID with a value for this attribute based on the Product Code submitted.

6.36 FDA Listing Number

FDA GUDID

Description	Number assigned by FDA during Registration and Listing to all devices in commercial distribution, regardless of pre-market authorization requirements per 21 CFR 807.28(f).
Data Entry Notes	Enter all relevant listing numbers that enable the labeler to commercially distribute the given version or model of device. Listing number is optional for HCT/P devices, Kits and IVDs with a BLA premarket number.
Edit Rules After Grace Period	Add (Addition of new data is allowed)
Required?	Conditionally Required* *Unless device is an HCT/P, kit or IVD with a BL premarket submission number
Data Type & Length	Type: Alphanum. Length: 7
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Private

GS1 GDSN (Temporary population until final GDSN deployment)

Module	AVP
Content	
Attribute/Role	fDAMedicalDeviceListing
Datatype/Secondary Class	String

© 2015 GS1 AISBL

Module	AVP
Multiplicity	Optional
Occurrence	Multiple
Definition	Most Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to list the devices that are made at their facility and the activities that are performed on those devices. Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.
Code List Name	N/A

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- fDAMedicalDeviceListingNumber. The GUDID is asking for the FPD Medical Device Listing number assigned to the device. It will be deployed into the GDSN Schema in 2016-17 into a final solution in the Additional Trade item Identification Type Code set of attributes..

This group attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Version or Model Number, Catalog Number, Secondary DI Number, DM DI Number, and FDA Listing Number.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but cannot be edited or deleted.

6.37 Code SPL Name - GMDN Preferred Term Code and FDA Preferred Term Code

FDA GUDID

Description	GMDN Preferred Term (PT) Code is a unique five-digit code used to identify common device types. This PT Code is assigned to medical devices and related health care products for the purposes of grouping and categorization. SPL Definition for GMDN Preferred Term (PT) Code: "Unique numerical five-digit number used to generically identify medical devices and related health care products." SPL Definition for FDA Preferred Term Code: "Unique four-character value assigned by the FDA to indicate a GMDN Preferred Term without exposing the GMDN PT Code."
Data Entry Notes	Enter all applicable GMDN Preferred Term Codes or FDA PT Codes. Each device record must have at least one assigned GMDN Code/FDA PT Code; DI records are allowed >1 GMDN Code/FDA PT Code, if necessary. Must enter GMDN Code OR FDA PT Code, please don't enter both codes for the same GMDN Name and Definition. For GMDN Codes: Enter only the 5-digit number, omit the 'P' For FDA PT Codes: Enter the 4-letter code. The FDA PT Codes are assigned to each GMDN term, used in place of a GMDN Code. They enable labelers to assign a GMDN term to their GUDID submission until a GMDN Code can be obtained from the GMDN Agency. The FDA PT Codes can be found in the Find FDA PT Code Module on the GUDID website. For more information, see the GUDID Final Guidance.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)

© 2015 GS1 AISBL

Description	GMDN Preferred Term (PT) Code is a unique five-digit code used to identify common device types. This PT Code is assigned to medical devices and related health care products for the purposes of grouping and categorization. SPL Definition for GMDN Preferred Term (PT) Code: "Unique numerical five-digit number used to generically identify medical devices and related health care products." SPL Definition for FDA Preferred Term Code: "Unique four-character value assigned by the FDA to indicate a GMDN Preferred Term without exposing the GMDN PT Code."
Required?	Required, SPL Text: "Required - either GMDN PT Code or FDA PT Code"
Data Type & Length	Type: Num. Length: 5, SPL Text: "Alphanumeric, 5"
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Private

GS1 GDSN (requires 2 GDSN attributes to denote the GUDID FDA Premarket Submission Number)

Module	GDSNTradeItemClassification
Content	Attribute
Attribute/Role	AdditionalTradeItemClassificationSystemCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Single
Definition	The Classification System for the Additional Trade Item Classification.
Code List Name	AdditionalTradeItemClassificationCodeListCode (“35” for GMDN or “65” for FDA PT Code)

Module	TradeItemClassification
Content	Attribute
Attribute/Role	additionalTradeItemClassificationCode
Datatype/Secondary Class	AdditionalTradeItemClassificationCode
Multiplicity	Optional
Occurrence	Multiple
Definition	Category code based on alternate classification schema chosen in addition to the Global Product Classification (GPC).
Code List Name	N/A

Population Guidance (below)

This repeatable set of attributes will allow for the population of a GMDN Code or a FDA PT Code for the device. This can be accomplished by the population of the code value “35” (for GMDN) and/or “65” (for FDA PT Code) in the GDSN attribute AdditionalTradeItemClassificationSystemCode . The actual GMDN Code or FDA PT Code can then be populated using the associated value in the GDSN attribute additionalTradeItemClassificationCode. Only the GMDN Preferred Term will be populated in the GUDID.

This set of attributes will also be used to populate several pieces of information- FDA Product Code, FDA Premarket Submission Number, FDA Preferred Term Code, and GMDN. For supply chain use, this set of attributes can also provide the UNSPSC codes for the device.

© 2015 GS1 AISBL

The SPL Guidance states "*As stipulated in the Final UDI Rule [78 FR 58786], FDA has developed a new GUDID module, Find FDA Preferred Term (PT) Codes, that will enable users to select a FDA PT Code to be used in their GUDID submission until a GMDN PT code can be obtained from the GMDN Agency. The Find FDA PT Code module is enabled in GUDID v1.1 and can be accessed via the GUDID Web Interface by Coordinator and Labeler Data Entry (LDE) Users of GUDID. Note: these FDA PT Codes only apply to GUDID cannot be used in place of GMDN PT Codes for any other system.*"

The population of a GMDN Code via GDSN has been available for some time. While the FDA will not make the code available to the Public in the GUDID, GDSN will pass the code along to normal GDSN recipients for their use following their existing processes. The FDA will use the code provided to access the GMDN Preferred Term from the current GMDN Codeset. While the GMDN Code will not be published on the FDA GUDID Portal, the applicable GMDN Preferred Term will be published.

6.38 Name

FDA GUDID

Description	Name associated with the GMDN Preferred Term Code /FDA PT Code.
Data Entry Notes	System populated based on GMDN Preferred Term Code/FDA PT Code.
Edit Rules After Grace Period	NA (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)
Required?	Auto Populated
Data Type & Length	NA
Entry List of Values (LOV)	NA
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	GDSNTradeItemClassification
Content	Attribute
Attribute/Role	additionalTradeItemClassificationCodeDescription
Datatype/Secondary Class	String (Text 1-200 characters)
Multiplicity	Optional
Occurrence	Single
Definition	Description of the additional classification bundle (code/agency + description).
Code List Name	N/A

Population Guidance (below)

The FDA will automatically populate the GUDID with a value for this attribute based on the GMDN Preferred Term Code submitted. Publishing the description field with the classification code name or description in GDSN will provide additional value to supply chain partners receiving GDSN messages.

The population of a GMDN Code via GDSN has been available for some time. While the FDA will not make the code available to the Public in the GUDID, GDSN will pass the code along to normal GDSN recipients for their use following their existing processes.

6.39 Definition

FDA GUDID

Description	Description associated with the GMDN Preferred Term Code/FDA PT Code.
Data Entry Notes	System populated based on GMDN Preferred Term Code/FDA PT Code

© 2015 GS1 AISBL

Description	Description associated with the GMDN Preferred Term Code/FDA PT Code.
Edit Rules After Grace Period	NA (data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element)
Required?	Auto Populated
Data Type & Length	N/A
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	N/A
Content	N/A
Attribute/Role	N/A
Datatype/Secondary Class	Auto Populated by FDA for the GUDID based on the GMDN Code.
Multiplicity	N/A
Occurrence	N/A
Definition	N/A
Code List Name	N/A
Attribute Name	N/A
Definition	N/A
Data Type	N/A
GDSN Required	1..1, Required

Population Guidance (below)

The FDA will automatically populate the GUDID with a value for this attribute based on the GMDN Preferred Term Code submitted.

6.40 For Single Use

FDA GUDID

Description	Indicates that the device is intended for one use or on a single patient during a single procedure.
Data Entry Notes	Choose Yes/No from the drop down list. (Webtool)
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Required
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Module	MedicalDeviceTradeItemModule
Content	Attribute
Attribute/Role	manufacturerDeclaredReusabilityTypeCode

© 2015 GS1 AISBL

Module	MedicalDeviceTradeItemModule
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Single
Definition	Determines if the product is intended for single or multiple uses, including the number of validated cycles and the number of times a product can be used according to the manufacturer specifications. It is suggested that medical providers consult the device manufacturer's Instruction For Use (IFU) for full reusability instructions.
Code List Name	HealthcareTradeItemReusabilityTypeCode

Population Guidance (below)

This GDSN attribute is a code list stating if the item can be used again. When a value of "SINGLE_USE" or "REUSABLE_SAME_PATIENT" are populated for the GDSN attribute manufacturerDeclaredReusabilityTypeCode, the GUDID will be populated with a value of "TRUE" signifying the device is intended for one use or multiple uses on a single patient. For all other values populated in the GDSN attribute manufacturerDeclaredReusabilityTypeCode, the GUDID will be populated with a value of "FALSE" signifying the device can be used more than one time on multiple patients.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be changed. Many of the data elements are locked and can no longer be edited.

6.41 Lot or Batch Number

FDA GUDID

Description	Indicates the device is managed by lot or batch number. This number can be found on the device label or packaging. Lot or Batch means one finished device or more that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.
Data Entry Notes	Choose Yes/No from the drop down list. For stand-alone software, select Yes to indicate that the software version number will be represented as a Lot or Batch number
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Required
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	PackagingMarkingModule
Content	Attribute
Attribute/Role	hasBatchNumber
Datatype/Secondary Class	Boolean
Multiplicity	Optional
Occurrence	Single

© 2015 GS1 AISBL

Module	PackagingMarkingModule
Definition	Indication whether the base trade item is batch or lot number requested by law, not batch or lot number requested by law but batch or lot number allocated, or not batch or lot number allocated. A batch or lot number is a manufacturer assigned code used to identify a trade item's trade item on batch or lot. Differs from Serial Number which is a manufacturer assigned code during the trade item on cycle to identify a unique trade item.
Code List Name	

Population Guidance (below)

This attribute is a Boolean clarifying how the item is controlled. It is not for the population of actual lot or batch numbers. Neither the GUDID nor GDSN are used to provide actual Batch or Lot numbers. These should be communicated in transactional documents such as packaging, shipping and invoice documents.

A value populated of “TRUE” signifies that the device has, as one of its controls, a batch or lot number. It also signifies that the batch or lot number will be printed on the packaging and be contained in the UDI.

6.42 Manufacture Date

FDA GUDID

Description	Indicates the device is managed by date of manufacture; the date a specific device was manufactured.
Data Entry Notes	Choose Yes/No from the drop down list. (Webtool)
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Required
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	PackagingMarkingModule
Content	Attribute
Attribute/Role	tradeItemDateOnPackagingTypeCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Single
Definition	Indicates the type of date marked on the packaging for example Best Before Date.
Code List Name	TradeItemDateOnPackagingTypeCode

Population Guidance (below)

This GUDID attribute is a Boolean clarifying how the item is controlled. It will be mapped from the code value “PRODUCTION_DATE” in the GDSN attribute tradeItemDateOnPackagingTypeCode. This attribute is not for the population of actual manufacturing dates. Neither the GUDID nor GDSN are used to provide actual manufacturing dates. These should be communicated in transactional documents such as packaging, shipping and invoice documents.

© 2015 GS1 AISBL

A value populated of “PRODUCTION_DATE” for the GDSN attribute tradeItemDateOnPackagingTypeCode signifies that the item has, as one of its controls, a manufacture date. It also signifies that the manufacture date will be printed on the packaging and be contained in the UDI.

6.43 Serial Number

FDA GUDID

Description	Indicates the device is managed by serial number. This number can be found on the device label or packaging. The serial number is assigned by the labeler and should be specific to each device.
Data Entry Notes	Choose Yes/No from the drop down list. (Webtool)
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Required
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	PackagingMarkingModule
Content	Attribute
Attribute/Role	serialNumberLocationCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Multiple
Definition	The location on the item or packaging of a serial number. A serial number is a code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime for example a Microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569.
Code List Name	SerialNumberLocationCode

Population Guidance (below)

This GUDID attribute is a Boolean clarifying how the item is controlled. It is not for the population of an actual serial number(s). Neither the GUDID nor GDSN are used to provide an actual serial numbers(s). These should be communicated in transactional documents such as packaging, shipping and invoice documents.

A GUDID value of “TRUE” signifies that the item has, as one of its controls, a serial number(s). It also signifies that the manufacture date will be printed on the packaging and in the UDI.

This GDSN attribute is a code list attribute designating where the serial number can be found on the item or its packaging, if present. If a value is populated for the GDSN attribute of “MARKED_ON_PACKAGING”, “MARKED_ON_PACKAGING_INSERT”, “UNSPECIFIED”, or “MARKED_ON_TRADE_ITEM”, it signifies that the item has, as one of its controls, a serial number and a value of “TRUE” will populated for the GUDID attribute. It also signifies that the serial number will be printed on the packaging, the device, and be contained in the UDI. Any other code value published in GDSN will populate a value of “FALSE” for the GUDID attribute.

© 2015 GS1 AISBL

6.44 By Expiration Date

FDA GUDID

Description	Indicates the device is managed by expiration date; the date by which the label of a device states that the device must or should be used.
Data Entry Notes	Choose Yes/No from the drop down list. (Webtool)
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Required
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	PackagingMarkingModule
Content	Attribute
Attribute/Role	tradeItemDateOnPackagingTypeCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Single
Definition	Indicates the type of date marked on the packaging for example Best Before Date.
Code List Name	TradeItemDateOnPackagingTypeCode

Population Guidance (below)

This GUDID attribute is a Boolean clarifying how the item is controlled. It will be mapped from the code values “EXPIRATION_DATE” or “BEST_BEFORE_DATE” in the GDSN attribute tradeItemDateOnPackagingTypeCode. This attribute is not for the population of actual expiration dates. Neither the GUDID nor GDSN are used to provide actual expiration dates. These should be communicated in transactional documents such as packaging, shipping and invoice documents.

A value populated of “EXPIRATION_DATE” or “BEST_BEFORE_DATE” for the GDSN attribute tradeItemDateOnPackagingTypeCode signifies that the item has, as one of its controls, an expiration date. It also signifies that the expiration date will be printed on the packaging and be contained in the UDI.

6.45 Donation Identification Number

FDA GUDID

Description	Indicates the device is managed by a Donation Identification Number. This number can be found on the device label or packaging. The Donation Identification Number is applicable to devices that are also regulated as HCT/Ps and is a number that is assigned to each donation.
Data Entry Notes	Choose Yes/No from the drop down list. This PI is only applicable to HCT/P products regulated as medical devices.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Required

© 2015 GS1 AISBL

Description	Indicates the device is managed by a Donation Identification Number. This number can be found on the device label or packaging. The Donation Identification Number is applicable to devices that are also regulated as HCT/Ps and is a number that is assigned to each donation.
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Module	AVP
Content	
Attribute/Role	donationIdentificationNumberMarked
Datatype/Secondary Class	Boolean
Multiplicity	Optional
Occurrence	Single
Definition	Indicates the device is managed by a Donation Identification Number. This number can be found on the device label or packaging. The Donation Identification Number is applicable to devices that are also regulated as HCT/Ps and is a number that is assigned to each donation.
Code List Name	N/A

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- donationIdentificationNumberMarked. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

This GUDID attribute is a Boolean clarifying how the item is controlled. It is not for the population of actual Donation Identification Numbers. Neither the GUDID nor GDSN are used to provide actual Donation Identification Numbers. These should be communicated in transactional documents such as packaging, shipping and invoice documents.

6.46 Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)

FDA GUDID

Description	Indicates that the device or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437. Choosing 'Yes' indicates that the device label or packaging contains one of the following statements: (1) "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions", (2) This Product Contains Dry Natural Rubber", (3) Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions" or (4) "The Packaging of This Product Contains Dry Natural Rubber".
Data Entry Notes	Choose Yes/No from the drop down list. (Webtool)
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Required
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	YES
Public/Private Status	Public

© 2015 GS1 AISBL

GS1 GDSN

Module	HealthcareItemInformationModule
Content	Attribute
Attribute/Role	doesTradeItemContainLatex
Datatype/Secondary Class	NonBinaryLogicEnumeration
Multiplicity	Optional
Occurrence	Single
Definition	An indication that the trade item has a positive latex reference on the Trade Item's labeling.
Code List Name	NonBinaryLogicEnumerationCode

Population Guidance (below)

This GDSN attribute is a Non-Binary Logic Code List with the values of "TRUE", "FALSE", "NOT_APPLICABLE", and "UNSPECIFIED". For the US Target Market, the only values, which can be used are "TRUE" and "FALSE" for medical devices. All other values should not be accepted for a GDSN Target Market value of 840 (US).

Application of the value is based upon whether a mark exists on the packaging as to latex being contained in the device or its packaging. If a mark is required to be on the package, this attribute is populated with "TRUE". If no mark is required, then this attribute is populated with "FALSE". This is based on Target Market regulation, such as in the US which basically states that if there is latex present a label mark must be placed on the packaging.

If there is not any Target Market regulations, the values of "NOT_APPLICABLE" and "UNSPECIFIED" may be used. In this case, the value of "UNSPECIFIED" will signify that the submitter of the GDSN Message is uncertain and may not have tested the device for latex content.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be changed. Many of the data elements are locked and can no longer be edited.

6.47 Device labeled as "Not made with natural rubber latex"

FDA GUDID

Description	"Indicates that natural rubber latex was not used as materials in the manufacture of the medical product and container and the device labeling contains this information. Only applicable to devices not subject to the requirements under 21 CFR 801.437. Not all medical products that are NOT made with natural rubber latex will be marked.
Data Entry Notes	Select checkbox if appropriate. Only applicable if the response to "Device required to be labeled as containing natural rubber latex or dry natural rubber" is "No". Optional element for labelers who include a statement of 'latex-free' on their label or in their labeling. FDA finds these statements: 'latex-free' and 'does not contain latex', to be not scientifically supportable and strongly recommends they not be used in medical product labeling. Instead FDA recommends the use of the statement 'Not made with natural rubber latex." It is not assumed that all devices NOT made with natural rubber latex are marked; therefore this is an optional element for the labelers who choose to make a statement in the labeling.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Optional
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	NA

© 2015 GS1 AISBL

Description	"Indicates that natural rubber latex was not used as materials in the manufacture of the medical product and container and the device labeling contains this information. Only applicable to devices not subject to the requirements under 21 CFR 801.437. Not all medical products that are NOT made with natural rubber latex will be marked.
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	HealthWellnessPackagingMarkingModule
Content	Attribute
Attribute/Role	packagingMarkedFreeFromCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Multiple
Definition	Indication of the food ingredients that the package is marked free from.
Code List Name	PackagingMarkedFreeFromCode (“FREE_FROM_LATEX”)

Population Guidance (below)

This GDSN attribute is a code list of values representing markings on the packaging. The markings signify the device is “Free-from” certain ingredients (irritants or allergens). This GDSN attribute is only populated to signify what is called out in one of these markings. The device might be free from one or more of the ingredients signified by a code value in the code list. However, the actual code value is only populated here if there is an actual mark on the package calling out the ingredient is not present.

If a value of “FREE_FROM_LATEX” is published in the GDSN attribute packagingMarkedFreeFromCode , a value of “TRUE” will be populated in the GUDID. Any other code value published in GDSN will populate a value of “FALSE” for this GUDID attribute.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be edited, but only under certain circumstances. See Edit Rules After Grace Period for more details

6.48 Prescription Use (Rx)

FDA GUDID

Description	Indicates that the device requires a prescription to use.
Data Entry Notes	Select checkbox if appropriate. Can select both Rx and OTC for one DI record. (Webtool)
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Optional If no data is provided, "No" is stored
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

© 2015 GS1 AISBL

GS1 GDSN

Module	SalesInformationModule
Content	Attribute
Attribute/Role	consumerSalesConditionCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Multiple
Definition	A code depicting restrictions imposed on the Trade Item regarding how it can be sold to the consumer for example Prescription Required.
Code List Name	ConsumerSalesConditionTypeCode (“PRESCRIPTION_REQUIRED”)

Population Guidance (below)

This GDSN attribute is a code list of values signifying how the item is presented for sale to a consumer.

If a value of “PRESCRIPTION_REQUIRED” is published in the GDSN attribute consumerSalesConditionCode attribute, a value of “TRUE” will be populate in the GUDID. Any other code value published in GDSN will populate a value of “FALSE” for this GUDID attribute.

6.49 Over the Counter (OTC)

FDA GUDID

Description	Indicates that the device does not require a prescription to use and can be purchased over the counter (OTC).
Data Entry Notes	Select checkbox if appropriate. Can select both Rx and OTC for one DI record. (Webtool)
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Optional If no data is provided, "No" is stored
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	NA
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	SalesInformationModule
Content	Attribute
Attribute/Role	consumerSalesConditionCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Multiple
Definition	A code depicting restrictions imposed on the Trade Item regarding how it can be sold to the consumer for example Prescription Required.
Code List Name	ConsumerSalesConditionTypeCode (“OTC”)

© 2015 GS1 AISBL

Population Guidance (below)

This GDSN attribute is a code list of values signifying how the item is presented for sale to a consumer.

If a value of “OTC” is published in the GDSN attribute consumerSalesConditionCode attribute, a value of “TRUE” will be populate in the GUDID. Any other code value published in GDSN will populate a value of “FALSE” for this GUDID attribute.

6.50 What MRI safety information does the labeling contain?

FDA GUDID

Description	Indicates the MRI Safety Information, if any, that is present in the device labeling. Please see the ASTM F2503-13 standard for more information.
Data Entry Notes	Choose a value from the drop down LOV. The final rule does not require MRI-compatibility testing; it only requires submission of information regarding MRI-compatibility that the labeler already possesses. (Webtool)
Edit Rules After Grace Period	Edit (Editing of entered data is allowed)* *ONLY if changing from 'Labeling does not contain…' to other MR status (Safe, Unsafe, Conditional (data element is not able to be changed directly; most are ‘auto-populated’ fields whose information depends on another data element)l). Otherwise, NO changes are allowed.
Required?	Required
Data Type & Length	N/A
Entry List of Values (LOV)	MR Safe, MR Unsafe, MR Conditional, Labeling does not contain MRI Safety information
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	MedicalDeviceTradeItemModule
Content	Attribute
Attribute/Role	mRICompatibilityCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Single
Definition	This is an identification of the compatibility of a trade item for use in the presence of a Magnetic Resonance Imaging (MRI) system.
Code List Name	MRICompatibilityCode

Population Guidance (below)

This GDSN attribute is a code list of values signifying if the device is safe for use in an MRI environment.

All GDSN code values map to an applicable GUDID code values. When “MRI_COMPATIBLE” is populated in GDSN, the value of “MR Conditional” will be provided to the GUDID. When “UNSPECIFIED” is populated in GDSN, the value of “Labeling does not contain MRI Safety Information” will be provided to the GUDID.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be edited, but only under certain circumstances. See Edit Rules After Grace Period for more details

© 2015 GS1 AISBL

6.51 Size Type

FDA GUDID

Description	Dimension type for the clinically relevant measurement of the medical device.
Data Entry Notes	Choose a value from the drop down LOV. If the desired Size Type is not in the current list, select 'Size Text, specify' and the data element 'Size Type Text' will appear (see below). It is expected that the 'Size Text, specify' will only be available for a limited time. Use this option to help us build a list of values that are appropriate for your device type. GUDID reserves the right to review all suggestions before adding values to the Size Type LOV. More than one Size Value per Type and more than one Size Type may be added to each DI record.
Edit Rules After Grace Period	Add (Addition of new data is allowed)
Required?	Conditionally Required* *If device is available in more than one size
Data Type & Length	N/A
Entry List of Values (LOV)	Circumference; Depth; Device Size Text, specify; Catheter Gauge ; Outer Diameter; Height; Length; Lumen/Inner Diameter; Needle Gauge; Total Volume; Width; Weight; Pressure; Pore Size; Area/Surface Area; Angle
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	AVP
Content	
Attribute/Role	clinicalSizeType (actual AVP name ends in 1, 2, 3, or 4 to allow grouping of AVP attributes)
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Size
Definition	The qualifier to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user. For example "needle gauge" for a 16 gauge needle, or "volume" for a 200 cc syringe.
Code List Name	

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- clinicalSizeType. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

All of the clinical attributes can be repeated as a group when this value changes. In the temporary solution, the attribute names end in the numbers 1, 2, 3, and 4. All of the attributes ending in the same number are in a group together and relate to each other. This numbering will be removed in the final GDSN solution.

This GUDID attribute is a Code List clarifying the qualifier (type) associated to the clinical size values. For example as syringe is measured by the gauge of the needle and/or the volume it can contain. For the type, this attribute might be populated with “NEEDLE_GAUGE” and/or “TOTAL_VOLUME”.

This attribute is part of a repeatable class of clinical attributes for the device containing the Size Type, Size Value and Size Unit of Measure for the device’s clinical size.

© 2015 GS1 AISBL

There is an option to specify a textual value for a clinical size type, which has not been specified in the value and UoM attributes.

When this attribute is published with the value of “DEVICE_SIZE_TEXT,_SPECIFY”, the GDSN attribute clinicalSizeText becomes required.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but cannot be edited or deleted.

6.52 Size Value

FDA GUDID

Description	Numeric value for the clinically relevant size measurement of the medical device.
Data Entry Notes	Enter numeric value for size. Decimals are accepted; fractions are not accepted. Each Size Value should be entered separately. GUDID is not accepting Size Value as a range at this time.
Edit Rules After Grace Period	Add (Addition of new data is allowed)
Required?	Conditionally Required* *Required if device is available in more than one size
Data Type & Length	Type: Num. Length: 40
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	AVP
Content	
Attribute/Role	clinicalSizeValue (actual AVP name ends in 1, 2, 3, or 4 to allow grouping of AVP attributes)
Datatype/Secondary Class	Measurement
Multiplicity	Optional
Occurrence	Single
Definition	The value to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user. For example 16 gauge for a needle, or 200 cc for a syringe. Carries a UoM from the Recommendation 20 code list.
Code List Name	UN Recommendation 20

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- clinicalSizeType. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

All of the clinical attributes can be repeated as a group when this value changes. In the temporary solution, the attribute names end in the numbers 1, 2, 3, and 4. All of the attributes ending in the same number are in a group together and relate to each other. This numbering will be removed in the final GDSN solution.

This GUDID attribute is a measurement attribute specifying the clinical measure of the device. This attribute is a numeric value and an associated Unit of Measure (UoM) qualifier. The UoM is a code

 © 2015 GS1 AISBL

from the UN Recommendation 20 Code List. The Data Pools will convert the UN Rec 20 code to the applicable code for the GUDID if needed. For the GUDID, the data pools will populate the numeric value in the GUDID attribute Size Value and the UoM qualifier in the GUDID attribute Size Unit of Measure.

For example, for a 16 gauge needle the value is 16 and the UoM is H79, for a 20 cc syringe the value is 20 and the UoM is CQM

This attribute is part of a repeatable class of clinical attributes for the device containing the Size Type, Size Value and Size Unit of Measure for the device's clinical size.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but cannot be edited or deleted.

6.53 Size Unit of Measure

FDA GUDID

Description	The unit of measure associated with each clinically relevant size. SPL Text: "The unit of measure associated with each clinically relevant size. The unit of measure must conform to UCUM standards."
Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Add (Addition of new data is allowed)
Required?	Conditionally Required* *Required if device is available in more than one size
Data Type & Length	N/A
Entry List of Values (LOV)	For length: Centimeter; Decimeter; Feet; Femtometer; Inch; Kilometer; Meter; Micrometer; Millimeter; Nanometer; Picometer; Yard; For area: Square centimeter; Square foot; Square inch; Square meter; Square millimeter For weight: Gram; Kilogram; Microgram; Milligram; Metric Ton; Pound; Ton For total volume: Centiliter; Cubic Inch; Cup; Deciliter; Femtoliter; Fluid Ounce; Gallon; Kiloliter; Liter; Microliter; Milliliter; Nanoliter; Picoliter; Pint; Quart For gauge: French; Gauge For angle: Degree For pressure: Pound per Square Inch; millibar; KiloPascal; Units per Liter; Hertz; Millibar SPL Text: "UCUM list of allowable values"
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	AVP
Content	
Attribute/Role	clinicalSizeValue (actual AVP name ends in 1, 2, 3, or 4 to allow grouping of AVP attributes)
Datatype/Secondary Class	Measurement
Multiplicity	Optional
Occurrence	Single
Definition	The value to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user. For example 16 gauge for a needle, or 200 cc for a syringe. Carries a UoM from the Recommendation 20 code list.

© 2015 GS1 AISBL

Module	AVP
Code List Name	UN Recommendation 20

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- clinicalSizeType. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

All of the clinical attributes can be repeated as a group when this value changes. In the temporary solution, the attribute names end in the numbers 1, 2, 3, and 4. All of the attributes ending in the same number are in a group together and relate to each other. This numbering will be removed in the final GDSN solution.

This GUDID attribute is a code list attribute specifying the clinical size unit of measure for the device's clinical size value. This attribute is a numeric value and an associated Unit of Measure (UoM) qualifier. The UoM is a code from the UN Recommendation 20 Code List. The Data Pools will convert the UN Rec 20 code to the applicable code for the GUDID if needed. For the GUDID, the data pools will populate the numeric value in the GUDID attribute Value and the UoM qualifier in the GUDID attribute Unit of Measure.

For example, for a 16 gauge needle the value is 16 and the UoM is H79, for a 20 cc syringe the value is 20 and the UoM is CQM

This attribute is part of a repeatable class of clinical attributes for the device containing the Size Type, Size Value and Size Unit of Measure for the device's clinical size.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but cannot be edited or deleted.

6.54 Size Type Text SPL Name: "Size Text"

FDA GUDID

Description	Additional undefined device size not represented in the GUDID Size Type LOV.
Data Entry Notes	Enter Size Type, Size Unit and Unit of Measure for each entry.
Edit Rules After Grace Period	Add (Addition of new data is allowed)
Required?	Conditionally Required* *Required if 'Size Text, specify' is selected above
Data Type & Length	Type: Alphanum. Length: 200
Entry List of Values (LOV)	NA
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	AVP
Content	
Attribute/Role	clinicalSizeText (actual AVP name ends in 1, 2, 3, or 4 to allow grouping of AVP attributes)
Datatype/Secondary Class	String
Multiplicity	Optional
Occurrence	Single

© 2015 GS1 AISBL

Module	AVP
Definition	When the clinicalSizeType is coded as "DEVICE_SIZE_TEXT_SPECIFY", this is the text used to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user.
Code List Name	

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- clinicalSizeType. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

All of the clinical attributes can be repeated as a group when this value changes. In the temporary solution, the attribute names end in the numbers 1, 2, 3, and 4. All of the attributes ending in the same number are in a group together and relate to each other. This numbering will be removed in the final GDSN solution.

This attribute provides a value for this attribute when the GDSN attribute clinicalSizeType is required to be populated when a value of “OTHER” or “DEVICE_SIZE_TEXT,_SPECIFY” is published in the GDSN attribute clinicalSizeType. This is free text field and should only be used if the clinical size cannot be specified using specific values in the Clinical Size Type Code List.

This attribute is part of a repeatable class of clinical attributes for the device containing the Size Type, Size Value and Size Unit of Measure for the device’s clinical size.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but cannot be edited or deleted.

6.55 Storage and Handling Type

FDA GUDID

Description	Indicates storage and handling requirements that are required for the device including temperature, humidity, and atmospheric pressure. SPL Definition: "Indicates storage requirements are required for the device, including: temperature, humidity, etc."
Data Entry Notes	Choose a value from the drop down LOV. Conditions of the Storage and Handling Type are measured below as a range, with a Low Value and a High Value. More than one Storage and Handling Type can be added per device record.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Optional
Data Type & Length	N/A
Entry List of Values (LOV)	Handling Environment Atmospheric Pressure; Handling Environment Humidity; Handling Environment Temperature; Special Storage Conditions; Storage Environment Atmospheric Pressure; Storage Environment Humidity; Storage Environment Temperature
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (for the GUDID temperature values)

Module	TradeItemTemperatureInformationModule
Content	Attribute

© 2015 GS1 AISBL

Module	TradeItemTemperatureInformationModule
Attribute/Role	temperatureQualifierCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Single
Definition	Code qualifying the type of a temperature requirement for example Storage.
Code List Name	TemperatureQualifierCode

GS1 GDSN (for the GUDID humidity values)

Module	TradeItemHumidityInformationModule
Content	Attribute
Attribute/Role	humidityQualifierCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Single
Definition	Code qualifying the type of a temperature requirement for example Storage.
Code List Name	TemperatureQualifierCode

GS1 GDSN (for the GUDID pressure values, use of any of these attributes below will point to GUDID pressure values)

Module	AVP
Content	
Attribute/Role	storageEnvironmentAtmosphericPressureMaximum
Datatype/Secondary Class	Measurement
Multiplicity	Optional
Occurrence	Single
Definition	The maximum pressure at which the trade item can be stored and handled. This uses a measurement consisting of a unit of measure and a value
Code List Name	

Module	AVP
Content	
Attribute/Role	storageEnvironmentAtmosphericPressureMinimum
Datatype/Secondary Class	Measurement
Multiplicity	Optional
Occurrence	Single
Definition	The minimum pressure at which the trade item can be stored and handled. This uses a measurement consisting of a unit of measure and a value
Code List Name	

Module	AVP
Content	

© 2015 GS1 AISBL

Module	AVP
Attribute/Role	trasnportationEnvironmentAtmosphericPressMax
Datatype/Secondary Class	Measurement
Multiplicity	Optional
Occurrence	Single
Definition	The maximum atmospheric pressure in which the item should be transported to remain usable. This value is the value above which the trade item should not be subjected.
Code List Name	

Module	AVP
Content	
Attribute/Role	transportationEnvironmentAtmosphericPressMin
Datatype/Secondary Class	Measurement
Multiplicity	Optional
Occurrence	Single
Definition	The minimum atmospheric pressure in which the item should be transported to remain usable. This value is the value above which the trade item should not be subjected.
Code List Name	

Population Guidance (below)

This GUDID attribute will have several different mappings from GDSN based on the needed piece of information.

To provide Temperature information to the GUDID, the GDSN attribute teperatureQualifierCode is in a repeatable group of attributes which include minimumTemperature, maximumTemperature, and temperatureMeasurementUnitCode. Combined this group will provide the full complement of information for the specified qualifier. For the GDSN qualifier value of “STORAGE_HANDLING”, the GUDID values for Storage Environment Temperature will be provided. For the GDSN qualifier value of “TRANSPORTATION”, the GUDID values for Handling Environment Temperature will be provided

To provide Humidity information to the GUDID, the GDSN attribute humidityQualifierCode is in a repeatable group of attributes which include minimumHumidityPercentage, and maximumHumidityPercentage. Combined this group will provide the full complement of information for the specified qualifier. For the GDSN qualifier value of “STORAGE_HANDLING”, the GUDID values for Storage Environment Humidity will be provided. For the GDSN qualifier value of “TRANSPORTATION”, the GUDID values for Handling Environment Humidity will be provided.

The GDSN attributes correlating to the GUDID attributes for atmospheric pressure are temporary attributes (AVP) in GDSN. They will be deployed into the GDSN Schema in 2016-17 into a final solution. The GDSN attributes are in two pairs. One pair is for the GUDID storage pressure attributes (storageEnvironmentAtmosphericPressureMinimum, and storageEnvironmentAtmosphericPressureMaximum). The other pair is for the GUDID transportation pressure (transportationEnvironmentAtmosphericPressMin, and transportationEnvironmentAtmosphericPressMax). The applicable storage type can be derived from the attribute name.

The following grid maps the GUDID code value for Storage Type to the applicable GDSN Attributes for pressure:

GUDID Storage Type Code	GDSN Attributes	
Storage environment atmospheric pressure	storageEnvironmentAtmosphericPressureMaximum; storageEnvironmentAtmosphericPressureMinimum	AVP

© 2015 GS1 AISBL

GUDID Storage Type Code	GDSN Attributes	
Handling environment atmospheric pressure	transportationEnvironmentAtmosphericPressMaximum; transportationEnvironmentAtmosphericPressMinimum	AVP

For the GUDID, the GDSN attributes with “maximum” in their name will map the numeric value into the GUDID attribute High Value. The GDSN attributes with “minimum” in their name will map the numeric value into the GUDID attribute Low Value.

Some devices have a temperature, humidity, or pressure range (High/Max and Low/Min values). Some have a greater than or less than value and others have a single or recommended value. Population of all possibilities can be handled in the GDSN and the GUDID using the following chart:

Information Type Available	Populated In	Value
Range of Lowest to Highest	Minimum or Low Values Field	Lowest Value
	Maximum or High Values Field	Highest Value
Less Than a Value	Minimum or Low Values Field	Leave Null (provide no value)
	Maximum or High Values Field	Highest Value
Greater Than a Value	Minimum or Low Values Field	Lowest Value
	Maximum or High Values Field	Leave Null (provide no value)
Single or Recommended Value	Minimum or Low Values Field	Single/Same Value populated in both fields
	Maximum or High Values Field	

6.56 Low Value SPL Name: "Storage and Handling Low Value"

FDA GUDID

Description	Indicates the low value for storage and handling requirements. SPL Definition: "Indicates the low value for storage requirements, such as temperature, humidity, etc."
Data Entry Notes	Enter a number for Low Value. Must enter at least one value, Low or High but can enter both Low Value and High Value, if needed. When Storage and Handling value is a range, this is the lower end of that range When Storage and Handling value is less than a value, enter the number here. When Storage and Handling value is exactly a value, enter the value here and in Storage and Handling High Value
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Conditionally Required* *One value (Low or High) is required if Storage and Handling Type is added to the device record.
Data Type & Length	Type: Num. Length: 6
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (for the GUDID temperature values)

Module	TradeItemTemperatureInformationModule
Content	Attribute
Attribute/Role	minimumTemperature

© 2015 GS1 AISBL

Module	TradeItemTemperatureInformationModule
Datatype/Secondary Class	TemperatureMeasurement
Multiplicity	Optional
Occurrence	Single
Definition	The minimum temperature that a trade item can be held below defined by the manufacturer without affecting product safety or quality.
Code List Name	

GS1 GDSN (for the GUDID humidity values)

Module	TradeItemHumidityInformationModule
Content	Attribute
Attribute/Role	minimumHumidityPercentage
Datatype/Secondary Class	Decimal
Multiplicity	Optional
Occurrence	Single
Definition	The minimum humidity in percentages that the goods should be stored in.
Code List Name	

GS1 GDSN (for the GUDID pressure values, use of any of these attributes below will point to GUDID pressure values)

Module	AVP
Content	
Attribute/Role	storageEnvironmentAtmosphericPressureMinimum
Datatype/Secondary Class	Measurement
Multiplicity	Optional
Occurrence	Single
Definition	The minimum pressure at which the trade item can be stored and handled. This uses a measurement consisting of a unit of measure and a value
Code List Name	

Module	AVP
Content	
Attribute/Role	transportationEnvironmentAtmosphericPressMin
Datatype/Secondary Class	Measurement
Multiplicity	Optional
Occurrence	Single
Definition	The minimum atmospheric pressure in which the item should be transported to remain usable. This value is the value above which the trade item should not be subjected.
Code List Name	

Population Guidance (below)

This GUDID attribute will have several different mappings from GDSN based on the needed piece of information.

© 2015 GS1 AISBL

To provide Temperature information to the GUDID, the GDSN attribute teperatureQualifierCode is in a repeatable group of attributes which include minimumTemperature, maximumTemperature, and temperatureMeasurementUnitCode. Combined this group will provide the full complement of information for the specified qualifier. For the GDSN qualifier value of "STORAGE_HANDLING", the GUDID values for Storage Environment Temperature will be provided. For the GDSN qualifier value of "TRANSPORTATION", the GUDID values for Handling Environment Temperature will be provided

To provide Humidity information to the GUDID, the GDSN attribute humidityQualifierCode is in a repeatable group of attributes which include minimumHumidityPercentage, and maximumHumidityPercentage. Combined this group will provide the full complement of information for the specified qualifier. For the GDSN qualifier value of "STORAGE_HANDLING", the GUDID values for Storage Environment Humidity will be provided. For the GDSN qualifier value of "TRANSPORTATION", the GUDID values for Handling Environment Humidity will be provided.

The GDSN attributes correlating to the GUDID attributes for atmospheric pressure are temporary attributes (AVP) in GDSN. They will be deployed into the GDSN Schema in 2016-17 into a final solution. The GDSN attributes are in two pairs. One pair is for the GUDID storage pressure attributes (storageEnvironmentAtmosphericPressureMinimum, and storageEnvironmentAtmosphericPressureMaximum). The other pair is for the GUDID transportation pressure (transportationEnvironmentAtmosphericPressMin, and transportationEnvironmentAtmosphericPressMax). The applicable storage type can be derived from the attribute name.

The following grid maps the GUDID code value for Storage Type to the applicable GDSN Attributes for pressure:

GUDID Storage Type Code	GDSN Attributes	
Storage environment atmospheric pressure	storageEnvironmentAtmosphericPressureMaximum; storageEnvironmentAtmosphericPressureMinimum	AVP
Handling environment atmospheric pressure	transportationEnvironmentAtmosphericPressMaximum; transportationEnvironmentAtmosphericPressMinimum	AVP

For the GUDID, the GDSN attributes with "maximum" in their name will map the numeric value into the GUDID attribute High Value. The GDSN attributes with "minimum" in their name will map the numeric value into the GUDID attribute Low Value.

Some devices have a temperature, humidity, or pressure range (High/Max and Low/Min values). Some have a greater than or less than value and others have a single or recommended value. Population of all possibilities can be handled in the GDSN and the GUDID using the following chart:

Information Type Available	Populated In	Value
Range of Lowest to Highest	Minimum or Low Values Field	Lowest Value
	Maximum or High Values Field	Highest Value
Less Than a Value	Minimum or Low Values Field	Leave Null (provide no value)
	Maximum or High Values Field	Highest Value
Greater Than a Value	Minimum or Low Values Field	Lowest Value
	Maximum or High Values Field	Leave Null (provide no value)
Single or Recommended Value	Minimum or Low Values Field	Single/Same Value populated in both fields
	Maximum or High Values Field	

© 2015 GS1 AISBL

6.57 High Value SPL Name: "Storage and Handling High Value"

FDA GUDID

Description	Indicates storage and handling requirements that are required for the device including temperature, humidity, and atmospheric pressure. SPL Definition: "Indicates the high value for storage requirements, such as temperature, humidity, etc."
Data Entry Notes	Enter a number for High Value. Must enter at least one value, Low or High but can enter both Low Value and High Value, if needed. When Storage and Handling value is a range, this is the higher end of that range. When Storage and Handling value is greater than a value, enter the number here. When Storage and Handling value is exactly a value, enter the value here and in Storage and Handling Low Value.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Conditionally Required* *One value (Low or High) is required if Storage and Handling Type is added to the device record.
Data Type & Length	Type: Num. Length: 6
Entry List of Values (LOV)	NA
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN (for the GUDID temperature values)

Module	TradeItemTemperatureInformationModule
Content	Attribute
Attribute/Role	maximumTemperature
Datatype/Secondary Class	TemperatureMeasurement
Multiplicity	Optional
Occurrence	Single
Definition	The maximum temperature that a trade item can not exceed as defined by the manufacturer without affecting product safety or quality.
Code List Name	

GS1 GDSN (for the GUDID humidity values)

Module	TradeItemHumidityInformationModule
Content	Attribute
Attribute/Role	minimumHumidityPercentage
Datatype/Secondary Class	Decimal
Multiplicity	Optional
Occurrence	Single
Definition	The maximum humidity in percentages that the goods should be stored in.
Code List Name	

© 2015 GS1 AISBL

GS1 GDSN (for the GUDID pressure values, use of any of these attributes below will point to GUDID pressure values)

Module	AVP
Content	
Attribute/Role	storageEnvironmentAtmosphericPressureMaximum
Datatype/Secondary Class	Measurement
Multiplicity	Optional
Occurrence	Single
Definition	The maximum pressure at which the trade item can be stored and handled. This uses a measurement consisting of a unit of measure and a value
Code List Name	

Module	AVP
Content	
Attribute/Role	trasnportationEnvironmentAtmosphericPressMax
Datatype/Secondary Class	Measurement
Multiplicity	Optional
Occurrence	Single
Definition	The maximum atmospheric pressure in which the item should be transported to remain usable. This value is the value above which the trade item should not be subjected.
Code List Name	

Population Guidance (below)

This GUDID attribute will have several different mappings from GDSN based on the needed piece of information.

To provide Temperature information to the GUDID, the GDSN attribute teperatureQualifierCode is in a repeatable group of attributes which include minimumTemperature, maximumTemperature, and temperatureMeasurementUnitCode. Combined this group will provide the full complement of information for the specified qualifier. For the GDSN qualifier value of “STORAGE_HANDLING”, the GUDID values for Storage Environment Temperature will be provided. For the GDSN qualifier value of “TRANSPORTATION”, the GUDID values for Handling Environment Temperature will be provided

To provide Humidity information to the GUDID, the GDSN attribute humidityQualifierCode is in a repeatable group of attributes which include minimumHumidityPercentage, and maximumHumidityPercentage. Combined this group will provide the full complement of information for the specified qualifier. For the GDSN qualifier value of “STORAGE_HANDLING”, the GUDID values for Storage Environment Humidity will be provided. For the GDSN qualifier value of “TRANSPORTATION”, the GUDID values for Handling Environment Humidity will be provided.

The GDSN attributes correlating to the GUDID attributes for atmospheric pressure are temporary attributes (AVP) in GDSN. They will be deployed into the GDSN Schema in 2016-17 into a final solution. The GDSN attributes are in two pairs. One pair is for the GUDID storage pressure attributes (storageEnvironmentAtmosphericPressureMinimum, and storageEnvironmentAtmosphericPressureMaximum). The other pair is for the GUDID transportation pressure (transportationEnvironmentAtmosphericPressMin, and transportationEnvironmentAtmosphericPressMax). The applicable storage type can be derived from the attribute name.

The following grid maps the GUDID code value for Storage Type to the applicable GDSN Attributes for pressure:

© 2015 GS1 AISBL

GUDID Storage Type Code	GDSN Attributes	
Storage environment atmospheric pressure	storageEnvironmentAtmosphericPressureMaximum; storageEnvironmentAtmosphericPressureMinimum	AVP
Handling environment atmospheric pressure	transportationEnvironmentAtmosphericPressMaximum; transportationEnvironmentAtmosphericPressMinimum	AVP

For the GUDID, the GDSN attributes with “maximum” in their name will map the numeric value into the GUDID attribute High Value. The GDSN attributes with “minimum” in their name will map the numeric value into the GUDID attribute Low Value.

Some devices have a temperature, humidity, or pressure range (High/Max and Low/Min values). Some have a greater than or less than value and others have a single or recommended value. Population of all possibilities can be handled in the GDSN and the GUDID using the following chart:

Information Type Available	Populated In	Value
Range of Lowest to Highest	Minimum or Low Values Field	Lowest Value
	Maximum or High Values Field	Highest Value
Less Than a Value	Minimum or Low Values Field	Leave Null (provide no value)
	Maximum or High Values Field	Highest Value
Greater Than a Value	Minimum or Low Values Field	Lowest Value
	Maximum or High Values Field	Leave Null (provide no value)
Single or Recommended Value	Minimum or Low Values Field	Single/Same Value populated in both fields
	Maximum or High Values Field	

6.58 Unit of Measure SPL Name: "Storage and Handling Unit of Measure"

FDA GUDID

Description	The unit of measure associated with the storage and handling conditions.
Data Entry Notes	Choose a value from the drop down LOV. (Webtool)
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Conditionally Required* *Required if Storage and Handling Type is added to the device record
Data Type & Length	NA
Entry List of Values (LOV)	Degrees Celsius; Degrees Fahrenheit; Degrees Kelvin; Kilo Pascal; Percent (%) Relative Humidity, Millibar
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	
Content	
Attribute/Role	
Datatype/Secondary Class	

© 2015 GS1 AISBL

Module	
Multiplicity	
Occurrence	
Definition	
Code List Name	

Population Guidance (below)

Potential UoMs for these storage and handling values are listed in Section 5 FDA GUDID mapping to GS1 code values under the UoM portion.

GS1 GDSN (for the GUDID temperature values)

Module	TradeItemTemperatureInformationModule
Content	Attribute
Attribute/Role	temperatureMeasurementUnitCode
Datatype/Secondary Class	Code
Multiplicity	Mandatory (If Module invoked)
Occurrence	Single
Definition	Any standardized, reproducible unit that can be used to measure any physical property.
Code List Name	TemperatureMeasurementUnitCode

GS1 GDSN (for the GUDID humidity values)

Module	N/A
Content	N/A
Attribute/Role	N/A
Datatype/Secondary Class	Data Pool to always populate with a value of Percentage or Percent
Multiplicity	N/A
Occurrence	N/A
Definition	N/A
Code List Name	N/A

GS1 GDSN (for the GUDID pressure values, use of any of these attributes below will point to GUDID pressure values)

Module	AVP
Content	
Attribute/Role	storageEnvironmentAtmosphericPressureMaximum
Datatype/Secondary Class	Measurement
Multiplicity	Optional
Occurrence	Single
Definition	The maximum pressure at which the trade item can be stored and handled. This uses a measurement consisting of a unit of measure and a value
Code List Name	

Module	AVP
Content	

© 2015 GS1 AISBL

Module	AVP
Attribute/Role	trasnportationEnvironmentAtmosphericPressMax
Datatype/Secondary Class	Measurement
Multiplicity	Optional
Occurrence	Single
Definition	The maximum atmospheric pressure in which the item should be transported to remain usable. This value is the value above which the trade item should not be subjected.
Code List Name	

Population Guidance (below)

This GUDID attribute will have several different mappings from GDSN based on the needed piece of information.

To provide Temperature information to the GUDID, the GDSN attribute teperatureQualifierCode is in a repeatable group of attributes which include minimumTemperature, maximumTemperature, and temperatureMeasurementUnitCode. Combined this group will provide the full complement of information for the specified qualifier. For the GDSN qualifier value of “STORAGE_HANDLING”, the GUDID values for Storage Environment Temperature will be provided. For the GDSN qualifier value of “TRANSPORTATION”, the GUDID values for Handling Environment Temperature will be provided

To provide Humidity information to the GUDID, the GDSN attribute humidityQualifierCode is in a repeatable group of attributes which include minimumHumidityPercentage, and maximumHumidityPercentage. Combined this group will provide the full complement of information for the specified qualifier. For the GDSN qualifier value of “STORAGE_HANDLING”, the GUDID values for Storage Environment Humidity will be provided. For the GDSN qualifier value of “TRANSPORTATION”, the GUDID values for Handling Environment Humidity will be provided.

The GDSN attributes correlating to the GUDID attributes for atmospheric pressure are temporary attributes (AVP) in GDSN. They will be deployed into the GDSN Schema in 2016-17 into a final solution. The GDSN attributes are in two pairs. One pair is for the GUDID storage pressure attributes (storageEnvironmentAtmosphericPressureMinimum, and storageEnvironmentAtmosphericPressureMaximum). The other pair is for the GUDID transportation pressure (transportationEnvironmentAtmosphericPressMin, and transportationEnvironmentAtmosphericPressMax). The applicable storage type can be derived from the attribute name.

The value provided for the GUDID Unit of Measure will be based on several different GDSN attributes. For temperatures, the value provided in the GDSN attribute temperatureMesurementUnitCode will be mapped to the GUDID. For pressures, the unit of measure value populated as part of the GDSN temporary attributes transportationEnvironmentAtmosphericPressMin, transportationEnvironmentAtmosphericPressMax, storageEnvironmentAtmosphericPressuerMinimum, and storageEnvironmentAtmosphericPressureMaximum will be mapped to the GUDID. For humidity, the data pool will auto-populate the GUDID with a value of percentage or percent.

Special Storage Conditions

FDA GUDID

Description	Indicates any special storage requirements for the product. SPL Text: "Indicates any special storage requirements for the product."
Data Entry Notes	Enter any other storage conditions. For devices kept at room temperature, or other standard conditions, input that information here.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)

© 2015 GS1 AISBL

Description	Indicates any special storage requirements for the product. SPL Text: "Indicates any special storage requirements for the product."
Required?	Conditionally Required* *Required if 'Special Storage Conditions' is selected above
Data Type & Length	Type: Alphanum. Length: 200
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	ConsumerInstructionsModule
Content	Attribute
Attribute/Role	consumerStorageInstructions
Datatype/Secondary Class	Description1000 (Free Text 1-1000 Characters) (Language Qualified)
Multiplicity	Optional
Occurrence	Multiple
Definition	Expresses in text the consumer storage instructions of a product which are normally held on the label or accompanying the product. This information may or may not be labeled on the pack. Instructions may refer to a suggested storage temperature, a specific storage requirement. Allows for the representation of the same value in different languages.
Code List Name	Language Code (ISO 639)

Population Guidance (below)

This attribute can be populated with any special storage, transportation, or handling instructions as deemed necessary by the Brand Owner.

6.59 Device Packaged as Sterile

FDA GUDID

Description	Indicates the medical device is free from viable microorganisms. See ISO/TS 11139.
Data Entry Notes	Choose Yes/No from the drop down list. The two Sterilization Method questions are independent of each other; this element is designed to capture information about the device as it enters Commercial Distribution. These data elements are not designed to capture sterilization procedures executed by the manufacturer or labeler.
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Required
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Module	MedicalDeviceTradeItemModule
Content	Attribute
Attribute/Role	initialManufacturerSterilizationCode

© 2015 GS1 AISBL

Module	MedicalDeviceTradeItemModule
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Multiple
Definition	Type(s) of sterilisation that may have been performed by the manufacturer if a trade item is sterile when it comes from the manufacturer. Sterilisation refers to any process that effectively kills or eliminates transmissible agents (such as fungi, bacteria, viruses, prions and spore forms etc.) from a surface, equipment, foods, medications, or biological culture medium. Some methods of sterilisation are through the application of heat, radiation, and ethylene.
Code List Name	SterilisationTypeCode

Population Guidance (below)

This GDSN attribute is a code list. If a value is published in GDSN, it indicates that the device is sold as being sterile. Therefore if a value is published in the GDSN attribute initialManufacturerSterilizationCode, then a value of “TRUE” will be populated in the GUDID. If no value is published in GDSN, then a value of “FALSE” will be populated in the GUDID.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be changed. Many of the data elements are locked and can no longer be edited.

6.60 Requires Sterilization Prior to Use

FDA GUDID

Description	Indicates that the device requires sterilization prior to use.
Data Entry Notes	Choose Yes/No from the drop down list. The two Sterilization Method questions are independent of each other; this element is designed to capture information about the device before it can safely encounter a patient, regardless of whether the device is single use or reused after reprocessing. These data elements are not designed to capture sterilization procedures executed by the manufacturer or labeler. If answered 'Yes', at least one Sterilization Method (below) must be selected.
Edit Rules After Grace Period	None (NO edit, add, or delete are allowed)
Required?	Required
Data Type & Length	Type: Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	MedicalDeviceTradeItemModule
Content	Attribute
Attribute/Role	initialSterilisationPriorToUseCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Multiple
Definition	This is an indication of the type(s) of sterilisation that is required to be completed by a healthcare provider prior to initial use of the healthcare trade item. Sterilisation refers to any process that effectively kills or eliminates transmissible agent

© 2015 GS1 AISBL

Module	MedicalDeviceTradeItemModule
Code List Name	SterilizationTypeCode

Population Guidance (below)

The GDSN attribute initialSterilirilizationPriorToUseCode is a code list indicating the type(s) of sterilization which should be performed on a device by a Provider prior to use. Population of a value for this attribute signifies that the device is not sold as sterile and that the Provider does need to sterilize it prior to use, using the method populated. If a code value is published in the GDSN, then a value of “TRUE” will be populated in the GUDID for Requires Sterilization Prior to Use. If no value is published in GDSN, then a value of “FALSE” will be populated in the GUDID.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be changed. Many of the data elements are locked and can no longer be edited.

6.61 Sterilization Method

FDA GUDID

Description	Indicates the method(s) of sterilization that can be used for this device.
Data Entry Notes	Choose a value from the drop down LOV. Only applicable if the answer to 'Requires Sterilization Prior to Use' is 'Yes'; otherwise, the LOV will remain inactive. The Entry LOVs represent the sterilization methods recognized by the CDRH Infection Control Branch. Methods selected should be only those approved for each device by the CDRH Office of Device Evaluation.
Edit Rules After Grace Period	Add (Addition of new data is allowed) Delete (Deletion of entered data is allowed) Edit (Editing of entered data is allowed)
Required?	Conditionally Required* *if 'Requires Sterilization Prior to Use' is marked 'Yes'
Data Type & Length	NA
Entry List of Values (LOV)	Chlorine Dioxide; Dry Heat; Ethylene Oxide; High Intensity Light or Pulse Light; Hydrogen Peroxide; Microwave Radiation; Moist Heat or Steam; Ozone; Peracetic Acid; Radiation; Sound Waves; Ultraviolet Light
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Module	MedicalDeviceTradeItemModule
Content	Attribute
Attribute/Role	initialSterilisationPriorToUseCode
Datatype/Secondary Class	Code
Multiplicity	Optional
Occurrence	Multiple
Definition	This is an indication of the type(s) of sterilisation that is required to be completed by a healthcare provider prior to initial use of the healthcare trade item. Sterilisation refers to any process that effectively kills or eliminates transmissible agent
Code List Name	SterilizationTypeCode

© 2015 GS1 AISBL

Population Guidance (below)

The GDSN attribute initialSterilirilizationPriorToUseCode is a code list indicating the type(s) of sterilization which should be performed on a device by a Provider prior to use. Population of a value for this attribute signifies that the device is not sold as sterile and that the Provider does need to sterilize it prior to use, using the method populated. When this attribute is published, a value of "TRUE" will be populated for the GUDID attribute Requires Sterilization Prior to Use. The value specified will be provided to the GUDID as the Sterilization Method. It is recommended to not use the value of UNSPECIFIED as the FDA GUDID will not accept that value.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be edited, but only under certain circumstances. See Edit Rules After Grace Period for more details

Note: Until the GDSN release can add these code values into the sterilisationMethodCodeList the GDSN AVP attribute for extendedInitialSterilzationPriorToUse can be used for them with these code values: Chlorine_Dioxide, Dry_Heat, High_Intensity_Or_Pulse_Light, Microwave_Radiation, Sound_Waves, High_Level_Disinfectant, Liquid_Chemical, Nitrogen_Dioxide, and Supercritical_Carbon_Dioxide

7 References

- For more information on UDI at a global level refer to *http://www.gs1.org/healthcare/udi*
- For more information on the IMDRF refer to *http://www.imdrf.org/*
- For more information on the U.S. FDA UDI refer to *http://www.gs1us.org/industries/healthcare/gs1-healthcare-us/fda-udi*
- For more information on the GDSN refer to *http://www.gs1.org/gdsn*
- For more information on GS1 Healthcare refer to *http://www.gs1.org/healthcare*
- For country support contact your local GS1 Member Organisation *http://www.gs1.org/contact*

For an interactive spreadsheet of the mapping from GDSN to FDA GUDID refer to *http://www.gs1us.org/gs1-us-library?Command=Core_Download&EntryId=747*

© 2015 GS1 AISBL